

EXHIBIT 7

EX-10.6 4 a2219480zex-10_6.htm EX-10.6

Exhibit 10.6

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

LICENSE AGREEMENT

BY AND BETWEEN

FOREST LABORATORIES HOLDINGS LIMITED

AND

ADAMAS PHARMACEUTICALS, INC.

DATED AS OF NOVEMBER 13, 2012

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT is entered into this 13th day of November, 2012 (the “Effective Date”), by and between Forest Laboratories Holdings Limited, a corporation organized under the laws of the Republic of Ireland, having a business address at Cumberland House, 9th Floor, 1 Victoria Street, Hamilton HM11, Bermuda (“Forest”), an indirect, wholly owned subsidiary of Forest Laboratories, Inc. (“Forest Parent”), and Adamas Pharmaceuticals, Inc., a corporation organized under the laws of the State of Delaware, having a business address at 2200 Powell Street, Suite 220, Emeryville, California 94608 (“Adamas”).

WHEREAS, Adamas has developed rights to Adamas Know-How (as hereinafter defined) and Adamas Patent Rights (as hereinafter defined); and

WHEREAS, Forest desires to obtain a license under the Adamas Patent Rights, Adamas Product Trademark Rights and the Adamas Know-How to Develop, Manufacture and Commercialize Products (as hereinafter defined), under the terms and conditions set forth herein, and Adamas desires to grant such a license.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE I

DEFINITIONS

The following terms, whether used in the singular or plural, shall have the following meanings:

- 1.1 “Act”. Act means both the US Federal Food, Drug, and Cosmetic Act, as amended from time to time, and the regulations promulgated under the foregoing.
- 1.2 “Adamas Donepezil Formulation”. Adamas Donepezil Formulation means: (a) that certain [*] formulation of Donepezil existing as of the Effective Date that is proprietary to Adamas, as transferred by Adamas to Forest after the Effective Date pursuant to Section 3.1(c), and (b) any Adamas Donepezil Formulation Modifications.
- 1.3 “Adamas Donepezil Formulation Modification”. Adamas Donepezil Formulation Modification has the meaning set forth in Section 4.1.
- 1.4 “Adamas Ex-US Patent Rights”. Adamas Ex-US Patent Rights means all Patent Rights outside the Territory Controlled by Adamas or its Affiliates as of the Effective Date or at any time during the Term that are necessary or useful for the Development or Manufacture of any Product(s).
- 1.5 “Adamas Intellectual Property”. Adamas Intellectual Property means the Adamas Know-How and the Adamas Patent Rights.
- 1.6 “Adamas Know-How”. Adamas Know-How means subject to Section 2.1(d), all Know-How (a) Controlled by Adamas or its Affiliates as of the Effective Date; or (b) Controlled by Adamas or its Affiliates at any time after the Effective Date during the Term that (in the case

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of (b)) is developed, created, conceived or first reduced to practice by or on behalf of Adamas or its Affiliates in connection with the Development, Manufacture or Commercialization of the Product(s); in each case of (a) and (b) above, to the extent necessary for the Development, Manufacture or Commercialization of any Product(s). Without limiting the foregoing, all Know-How listed on Schedule 1.6 are included within Adamas Know-How. For clarity, the Adamas Know-How excludes the [*]. Any and all Adamas Donepezil Formulations are included as part of the Adamas Know-How, whether or not satisfying the other requirements of this definition.

1.7 “Adamas Memantine Patent Rights”. Adamas Memantine Patent Rights means those Adamas Patent Rights in the Territory that [*] and [*]. The Adamas Memantine Patent Rights as of the Effective Date are listed on Schedule 1.7.

1.8 “Adamas Patent Rights”. Adamas Patent Rights means subject to Section 2.1(d), all Patent Rights in the Territory that (a) are Controlled by Adamas or its Affiliates as of the Effective Date or at any time during the Term and (b) are necessary or useful for the Development, Manufacture or Commercialization of any Product(s). For clarity, the Parties acknowledge that Adamas owns certain Patent Rights as of the Effective Date that are [*], but [*] (“Related Adamas Patent Rights”); consequently, the Parties agree that such Related Adamas Patent Rights are [*] and that [*] (except as expressly set forth in Section [*] or as otherwise expressly provided herein), under this Agreement with respect to such Related Adamas Patent Rights, as long as [*]. The Adamas Patent Rights shall [*] and to the extent [*] and [*]. For clarity, the Adamas Patent Rights exclude the [*].

1.9 “Adamas Product Trademark Rights”. Adamas Product Trademark Rights means: (a) the Trademark Rights with respect to the ARIMENDA™ trade mark that are Controlled by Adamas or its Affiliates; and (b) the domain names Controlled by Adamas incorporating the ARIMENDA™ trade mark as their URL address or any part of such address for domains (other than country-specific domains outside the Territory), in each case, as listed on Schedule 1.9.

1.10 “Affiliate”. Affiliate means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, “control” (including, with correlative meanings, “controlled by”, “controlling” and “under common control with”) means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of

securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities or other comparable equity interests. For clarity, neither of the Parties shall be deemed to be an “Affiliate” of the other.

1.11 “Authorized Generics”. Authorized Generics means, with respect to a particular Product being sold in a particular country, a pharmaceutical product that (a) is the same formulation and [*] the applicable Product, (b) is Commercialized by Forest, its Affiliate or a Third Party that has been granted a right to sell such pharmaceutical product by Forest or its Affiliates or Sublicensees under an NDA for such Product for which Forest, its Affiliate or Sublicensee is the applicant, (c) is [*] such Product (as sold by Forest and its Affiliates [*]), and (d) [*] for such Product (other than [*]).

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1.12 “Bankruptcy Code”. Bankruptcy Code means Title 11 of the US Code, as amended from time to time.

1.13 “Business Day”. Business Day means a day that is not a Saturday, Sunday or a day on which banking institutions in New York, New York or Dublin, Ireland are authorized by Law to remain closed.

1.14 “Calendar Quarter”. Calendar Quarter means each of the periods ending on March 31, June 30, September 30 and December 31 of any Calendar Year.

1.15 “Calendar Year”. Calendar Year means each calendar year during the Term.

1.16 “Change of Control”. Change of Control means, with respect to a Party or other Person:

(a) the bona fide acquisition by any Person or group (within the meaning of Sections 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934) of beneficial ownership of any capital stock of such Party (or any direct or indirect parent thereof), if after such acquisition, such Person or group would be the “beneficial owner” (as defined in Rule 13d-3 under the Securities Exchange Act of 1934), directly or indirectly, of securities of such Party or any direct or indirect parent of such Party representing more than fifty percent (50%) of the combined voting power of such Party’s then-outstanding securities entitled to vote generally in the election of directors;

(b) the consummation after approval by a Party’s (or any direct or indirect parent’s thereof) stockholders of a bona fide merger or consolidation of such Party (or any direct or indirect parent thereof), with any other Person, other than a merger or consolidation which would result in such Party’s (or any direct or indirect parent’s thereof) voting securities outstanding immediately prior to such consummation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the combined voting power of such Party’s (or any direct or indirect parent’s thereof) voting securities or such surviving entity’s voting securities outstanding immediately after such merger or consolidation; or

(c) the bona fide sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by a Party (or any direct or indirect parent thereof) of all or substantially all the assets of such Party.

1.17 “Cholinesterase Inhibitor”. Cholinesterase Inhibitor means a drug or compound that has as a mode of pharmacological activity the inhibition of any cholinesterase enzyme from breaking down acetylcholine (which such mode of pharmacological activity is not incidental to its primary mode of pharmacological activity).

1.18 “Commercialization” or “Commercialize”. Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, Manufacturing commercial supplies of, distributing, importing, offering for sale or selling a product. For clarity, Commercialization includes conducting Phase IV Clinical Trials.

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1.19 “Commercially Reasonable Efforts”. Commercially Reasonable Efforts means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party (including the efforts of its Affiliates and, in the case of Forest, its Sublicensees) of the type to accomplish such objective that [*] would normally use to accomplish a similar objective, and, specifically with respect to obligations hereunder relating to a Product, the carrying out of such obligations with those efforts and resources that [*] would use in Developing or Commercializing its own pharmaceutical products that are of similar market potential as the Product, in each case taking into account product labeling or anticipated labeling, present and future market potential, past performance of the Product, financial return, medical and clinical considerations, the extent of legal exclusivity relating to such Product, present and future regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due.

1.20 “Control” or “Controlled”. Control or Controlled means, with respect to any tangible property or intellectual property right or other intangible property, the possession (whether by ownership or license (other than pursuant to this Agreement)) by, (a) in the case of Adamas, Adamas or any of its Affiliates or (b) in the case of Forest, Forest or any of its Affiliates, as applicable, in each case ((a) and (b)) of the ability to grant to the other Party access to such tangible property or access to or a license or sublicense to such intellectual property right or other intangible property, as provided herein without violating the terms of any agreement with any Third Party; provided, however, that any subject matter, tangible property or intellectual property right or other intangible property shall not be considered Controlled by a Party or any of its Affiliates if it was Controlled by a Third Party acquirer of such Party (or an Affiliate of such a Third Party (excluding such Party or its Affiliates as of the Effective Date)) (collectively, the “Acquirer”) immediately prior to the date of the closing or consummation of such Change of Control of such Party, nor shall any improvement thereto or other subject matter that was developed by the Acquirer after such Change of Control, in each case, without use of any Confidential Information comprising Know-How of the Party that is subject to the Change of Control (or of an entity that was an Affiliate thereof prior to the Change of Control) or the Confidential Information comprising Know-How of the other Party, in each case, unless such use is [*]. In addition, if rights to a Party’s Know-How were granted to the Acquirer prior to its Change of Control (“Pre-Change of Control Rights”), then the use of such Party’s Know-How in accordance with such grant (and consistent with the exclusive licenses granted under this Agreement) shall not be deemed use of Know-How by the Acquirer for purposes of the foregoing; provided that such Pre-Change of Control Rights were granted in a separate transaction prior to the Change of Control that would permit exercise of the licenses even in the absence of the Change of Control and were not granted immediately preceding the Change of Control or in order to exempt the Acquirer from the provisions of this Section 1.20.

1.21 “Cover”, “Covering” or “Covered”. Cover, Covering or Covered means, with respect to a compound, product, technology, process or method that, in the absence of ownership of or a license granted under a Valid Claim or Patent Right, as the case may be, the manufacture, use, offer for sale, sale or importation of such compound or product or the practice of such technology, process or method would infringe such Valid Claim or Patent Right (or, in the case of a claim in a Patent Right that has not yet issued, would infringe such claim if it were to issue without modification).

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1.22 “CREATE Act”. CREATE Act means the Cooperative Research and Technology Enhancement Act of 2004, as codified in 35 U.S.C. §§ 103(c)(2)-(c)(3) or, after March 16, 2013, 35 U.S.C. § 102(c) as set forth in the Leahy-Smith America Invents Act of 2011.

1.23 “Detail”. Detail means that part of [*] sales call during which a sales representative of Forest or any of its Affiliates or Sublicensees makes a presentation of the FDC Franchise to a physician or other medical professional with prescribing authority (including a nurse practitioner or physician assistant with prescribing authority) provided, that the [*]. A “Primary Detail” means a Detail during a sales call in which the FDC Franchise is presented first and a “Secondary Detail” means a Detail during a sales call in which the FDC Franchise is presented second.

1.24 “Development” or “Develop”. Development or Develop means pre-clinical and clinical drug development activities with respect to Memantine or any Product, including IND-enabling toxicology and other IND-enabling pre-clinical development efforts, stability testing, process development, compound property optimization, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, Manufacturing supplies of compounds and products for pre-clinical and clinical use, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies, but excluding Phase IV Clinical Trials), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.25 “Development Plan”. Development Plan means the plan for the Development of the Memantine-Donepezil FDC Products in the Field as agreed to by the Parties in writing as of the Effective Date (the “Initial Development Plan”), as it may be modified from time to time in accordance with this Agreement. The Initial Development Plan is hereby incorporated into this Agreement by reference.

1.26 “DM104”. DM104 means that certain clinical study of Memantine-Donepezil FDC Product designated as such in the Development Plan, as may be modified from time to time in accordance with this Agreement, a synopsis of which is set forth in the Development Plan.

1.27 “DM105”. DM105 means that certain clinical study of Memantine-Donepezil FDC Product designated as such in the Development Plan, as may be modified from time to time in accordance with this Agreement, a synopsis of which is set forth in the Development Plan.

1.28 “DM303”. DM303 means that certain clinical study of Memantine-Donepezil FDC Product designated as such in the Development Plan, as may be modified from time to time in accordance with this Agreement, a synopsis of which is set forth in the Development Plan.

1.29 “DM304”. DM304 means that certain clinical study of Memantine-Donepezil FDC Product designated as such in the Development Plan, as may be modified from time to time in accordance with this Agreement, a synopsis of which is set forth in the Development Plan.

1.30 “DOJ”. DOJ means the US Department of Justice.

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1.31 “Donepezil”. Donepezil means that certain compound known as donepezil with a chemical structure specified in Schedule 1.31 and each prodrug, solvate, hydrate, ester, salt, stereoisomer, racemate, tautomer, polymorph and metabolite thereof.

1.32 “Donepezil [*]”. Donepezil [*] means [*] Donepezil in the Adamas Donepezil Formulation existing as of the Effective Date.

1.33 “End of Phase II Meeting”. End of Phase II Meeting means that certain end of phase II meeting between Adamas and the FDA with respect to Adamas’ IND for the Memantine-Donepezil FDC Product [*].

1.34 “End of Phase II Meeting Minutes”. End of Phase II Meeting Minutes means the official written minutes of the End of Phase II Meeting as provided to Adamas by the FDA [*].

1.35 “ER Product”. ER Product means a Product containing an extended release formulation of Memantine as its sole active ingredient. For clarity, Namenda shall not constitute an ER Product, but Namenda XR shall constitute an ER Product.

1.36 “FDA”. FDA means the US Food and Drug Administration and any successor agency.

1.37 “FDC Franchise”. FDC Franchise means (a) an FDC Product or (b) an FDC Product and Namenda XR.

1.38 “FDC Product”. FDC Product means a fixed dose combination product that contains both Memantine and a Cholinesterase Inhibitor as its sole active ingredients.

1.39 “Field”. Field means the prevention, treatment, control, mitigation or palliation of diseases or conditions in humans.

1.40 “First Commercial Launch”. First Commercial Launch means: (a) with respect to Forest, with respect to a Product in the Territory, the first shipment of such Product in commercial quantities for commercial sale by Forest, its Affiliates or its Sublicensees to a Third Party after approval of the NDA therefor by the FDA and (b) with respect to Adamas, with respect to a Product in a particular country or region, the first shipment of such Product in commercial quantities for commercial sale by Adamas, its Affiliates or its (sub)licensees to a Third Party after receipt of Regulatory Approval therefor by the applicable Regulatory Authority in such country or region.

1.41 “Forest Intellectual Property”. Forest Intellectual Property means the Forest Patent Rights and Forest Know-How.

1.42 “Forest Know-How”. Forest Know-How means: all Know-How Controlled by Forest or its Affiliates at any time after the Effective Date during the Term that (a) is developed, created, conceived or first reduced to practice by or on behalf of Forest or its Affiliates in connection with the Development, Manufacture and Commercialization of Product(s) pursuant to this Agreement, including Program Data or (b) constitutes [*]. For clarity, the Forest Know-How shall include all Program Data, [*] and [*].

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1.43 “Forest Patent Rights”. Forest Patent Rights means: (a) all Patent Rights that are Controlled by Forest or its Affiliates at any time after the Effective Date during the Term and that Cover the Forest Know-How and (b) [*]. For clarity, Forest Patent Rights shall [*] to the extent [*].

1.44 “FTE”. FTE means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [*] hours per Calendar Year) of work performed by Adamas directly related to the activities for which reimbursement by Forest is sought hereunder, or a portion thereof on a proportional basis.

1.45 “FTE Cost”. FTE Cost means, for any period, the product of (a) the actual total FTEs (or applicable portion thereof) during such period, and (b) the applicable FTE Rate.

1.46 “FTE Rate”. FTE Rate means, with respect to any Adamas employee, [*] for an FTE during the period during which such FTE was performed, [*] an employee to perform an activity pursuant to this Agreement for which Adamas will seek reimbursement from Forest at the FTE Cost.

1.47 “Generic Competition.” Generic Competition, with respect to a Product in a particular country, shall exist, on a Calendar Quarter-by-Calendar Quarter basis, after Generic Launch of one or more Generic Versions of such Product in such country, in any particular Calendar Quarter in which: (a) with respect to Generic Versions approved for sale under Section 505(j) of the Act (or the foreign equivalent of Section 505(j) of the Act for Generic Versions approved outside the Territory), the aggregate unit volume of Generic Version(s) of such Product sold for any approved indications in such Calendar Quarter in such country is at least [*] of the total prescription unit volume of such Product and such Generic Version(s) combined, in the aggregate, in such country in such Calendar Quarter (as measured by IMS International or other agreed mechanism); or (b) with respect to Generic Versions approved for sale under Section 505(b)(2) of the Act (or the foreign equivalent of Section 505(b)(2) of the Act for Generic Versions approved outside the Territory), (i) the aggregate unit volume of Generic Version(s) of such Product sold for any approved indications in such Calendar Quarter in such country is at least [*] of the total prescription unit volume of such Product and such Generic Version(s) combined, in the aggregate, in such country in such Calendar Quarter (as measured by IMS International or other agreed mechanism), and (ii) the weighted average (by prescription volume) of the price for such Product in such country during such Calendar Quarter sold by Forest, its Affiliates or Sublicensees or Adamas, its Affiliates or (sub)licensees, as applicable, is below [*] of the weighted average (by prescription volume) of the price for such Product in the Calendar Quarter immediately preceding the launch of the first of such Generic Versions for such Product in such country.

1.48 “Generic Launch”. Generic Launch means, with respect to a Product, the first commercial sale of a Generic Version of such Product, which sale is not authorized directly (as an Authorized Generic or foreign equivalent thereof) or indirectly (through a chain of distribution) by: (a) with respect to a Product in the Territory, Forest or any of its Affiliates or Sublicensees; or (b) with respect to a Product outside the Territory, Adamas or any of its Affiliates or (sub)licensees.

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1.49 “Generic Version”. Generic Version of a Product in a particular country means any Product, other than a Product sold by or under authority of, directly (as an Authorized Generic or foreign equivalent thereof) or indirectly (through a chain of distribution), Forest or its Affiliates or Sublicensees with respect to a Product in the Territory, or by Adamas or its Affiliates or

(sub)licensees with respect to a Product outside the Territory, that: (a) with respect to a Generic Version approved for sale under Section 505(j) of the Act (or the foreign equivalent of Section 505(j) of the Act for Generic Versions approved outside the Territory), (i) is approved for sale in such country in reliance on the prior approval of such Product as determined by the applicable Regulatory Authority, or (ii) is substitutable for such Product under applicable Laws in such country by a pharmacist without the intervention of the prescribing physician, or (b) with respect to a Generic Version approved for sale under Section 505(b)(2) of the Act (or the foreign equivalent of Section 505(b)(2) of the Act for Generic Versions approved outside the Territory), (i) is approved for sale in such country in reliance on the prior approval of such Product as determined by the applicable Regulatory Authority, and (ii) is substitutable for such Product under applicable Laws in such country by a pharmacist without the intervention of the prescribing physician, and (c) is not sold under a Trademark Right Controlled by Forest, its Affiliate or Sublicensee or a Trademark Right Controlled by Adamas, its Affiliate or (sub)licensee, as applicable. Generic Version of a Product expressly excludes any Authorized Generics for such Product.

1.50 “Governmental Authority”. Governmental Authority means any US federal, state or local or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.51 “IND”. IND means an investigational new drug application filed with the FDA with respect to a Product, or an equivalent application filed with the Regulatory Authority of a country other than the US.

1.52 “Initial FDC Product”. Initial FDC Product means a Memantine-Donepezil FDC Product that combines the following two active ingredients (and no other active ingredients) in the following forms: (a) Memantine formulated as Namenda XR; and (b) Donepezil [*]. For clarity, the terms of this Section 1.52 are subject to the provisions of Section 4.1.

1.53 “Joint Intellectual Property”. Joint Intellectual Property means the Joint Know-How and Joint Patent Rights.

1.54 “Know-How”. Know-How means proprietary or non-public information or materials, whether patentable or not, including (a) ideas, discoveries, inventions, improvements or trade secrets, (b) pharmaceutical, chemical or biological materials, products or compositions, (c) tests, assays, techniques, data, methods, procedures, formulas or processes, (d) technical, medical, clinical, toxicological or other scientific data or other information relating to any of the foregoing, and (e) drawings, plans, designs, diagrams, sketches, specifications or other documents containing or relating to such information or materials.

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1.55 “Law” or “Laws”. Law or Laws means all laws, statutes, rules, regulations, orders, judgments or ordinances of any Governmental Authority.

1.56 “Losses”. Losses means any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, judgments, and settlement amounts (including special, indirect, incidental, and consequential damages, lost profits, and Third Party punitive and multiple damages), and (b) in connection with all of the items referred to in clause (a) above, any and all costs and expenses (including reasonable counsel fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened).

1.57 “Major Market”. Major Market means with respect to Forest, the United States, and with respect to Adamas, Japan, the United Kingdom, France, Germany, Spain or Italy.

1.58 “Manufacture” or “Manufacturing”. Manufacture or Manufacturing means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.59 “Memantine”. Memantine means that certain compound known as memantine with a chemical structure specified in Schedule 1.59 and each [*] thereof.

1.60 “Memantine-Donepezil FDC Product”. Memantine-Donepezil FDC Product means a fixed dose combination Product containing Memantine and Donepezil as its sole active ingredients.

1.61 “[*]”. [*] means [*] or any of [*].

1.62 “[*] Agreements”. [*] Agreements means that certain [*] Agreement entered into between [*], dated [*], relating to the [*] for the [*] (“[*] Agreement”), and that certain [*] Agreement entered into between [*], dated [*], relating to the [*] for the [*], each as amended from time to time consistent with this Agreement (“[*] Agreement”), in each case as amended, modified or qualified by the [*].

1.63 “Namenda”. Namenda means a pharmaceutical product containing immediate-release Memantine as its sole active ingredient and Commercialized by or on behalf of Forest under the trademark NAMENDA® as of the Effective Date and any improvements thereto that contain immediate-release Memantine as the sole active ingredient and are made by or on behalf of Forest, its Affiliates or Sublicensees on or after such date.

1.64 “Namenda XR”. Namenda XR means that certain ER Product containing extended-release Memantine as its sole active ingredient that has been Developed by Forest and approved by the FDA as of the Effective Date and any improvements thereto made by or on behalf of Forest, its Affiliates or Sublicensees on or after such date.

1.65 “NDA”. NDA means a New Drug Application as defined in the Act, filed with the FDA with respect to a Product.

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1.66 “Net Sales”. Net Sales means the gross amounts billed or invoiced by Forest, its Affiliates and Sublicensees to any Third Party that is not a Sublicensee with respect to sales of ER Products or Other Products (in the case of royalties under Section 6.4(b)) or FDC Products (in the case of royalties under Section 6.4(a) or Section 6.4(c)(ii), as the case may be) in the Territory, calculated in the same manner as reported in its audited financial statements, less the sum of the following for the applicable class of Products (*i.e.*, ER Products, Other Products or FDC Products, as the case may be):

[*].

Net Sales shall not include transfers or dispositions of Products for charitable, pre-clinical, clinical or regulatory purposes that are without material profit.

1.67 “Orange Book”. Orange Book means the Approved Drug Products with Therapeutic Equivalence Evaluation published by the FDA’s Center for Drug Evaluation and Research, as updated and modified from time to time.

1.68 “Other Product”. Other Product means any Product, other than an ER Product or FDC Product, but excluding Namenda.

1.69 “Party”. Party means either Adamas or Forest; “Parties” means both Adamas and Forest.

1.70 “Patent Rights”. Patent Rights means the rights and interest in and to (a) all issued patents and pending patent applications in any country, including provisional patent applications, in any country; (b) all patent applications that claim, directly or indirectly, priority to any patent or patent applications described in clause (a), including all provisionals, divisionals, continuations, continuations-in-part, patents of addition, renewals, continued prosecution applications and requests for continued examination; (c) any and all patents that have issued or in the future issue from any of the patent applications described in clause (a) or clause (b), including utility models, petty patents and design patents and certificates of invention; and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including any re-examination, registrations or confirmation patents, letters of patent and reissues thereof, or other extensions, or restorations of patent terms resulting from any other post-grant proceedings (including, without limitation, any proceedings that will come into effect through full implementation of the Leahy-Smith America Invents Act of 2011, and any supplementary protection certificates and the like), with respect to any of the patents or patent applications described in clause (a), clause (b), or clause (c).

1.71 “Payments”. Payments means royalties, milestones and other amounts payable by Forest to Adamas pursuant to this Agreement.

1.72 “Person”. Person means any natural person or any corporation, company, partnership, joint venture, firm, Governmental Authority or other entity, including a Party.

1.73 “Phase IV Clinical Trial”. Phase IV Clinical Trial means a human clinical trial conducted for purposes of further characterizing and supporting a Product for marketing but not

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for purposes of seeking Regulatory Approval or of otherwise fulfilling a requirement of a Regulatory Authority.

1.74 “Primary Detail Equivalent” or “PDE”. Primary Detail Equivalent or PDE means a primary Detail equivalent where (a) a Primary Detail has a value of 1.0 primary Detail equivalent and (b) a Secondary Detail has the value of [*] primary Detail equivalents.

1.75 “Product”. Product means any pharmaceutical preparation containing Memantine as a single active ingredient or in combination with one or more other active ingredient(s).

1.76 “Product Information”. Product Information means (a) all data generated by Adamas or its Affiliates under the Development Plan, (b) all Adamas Know-How that is a trade secret related to a Product and (c) any Adamas Know-How that is patentable.

1.77 “Program Data”. Program Data means collectively, all proprietary data and results that are generated by or on behalf of either Party on any Memantine-Donpezil FDC Product under the Development Plan, including DM104, DM105, DM303 and DM304 studies.

1.78 “Regulatory Approval”. Regulatory Approval means the granting, whether through lapse of time or otherwise, by the FDA or by a comparable Regulatory Authority of approval to market a drug product in a country in the Territory or other jurisdiction.

1.79 “Regulatory Authority”. Regulatory Authority means any Governmental Authority, including the FDA, with responsibility for granting licenses or approvals (with the exception of price approvals) necessary for the marketing and sale of pharmaceutical products in a country or region of the Territory.

1.80 “Regulatory Plan”. Regulatory Plan means the regulatory strategy with respect to the Development of Memantine-Donpezil FDC Product as agreed to by the Parties in writing as of the Effective Date, as it may be modified from time to time in accordance with this Agreement. The Regulatory Plan as agreed as of the Effective Date is attached hereto as Schedule 1.80.

1.81 “Sales Year”. Sales Year means, with respect to ER Products, FDC Products and Other Products (each, a “Product Category”), each successive twelve (12)-month period in which a Product within such Product Category is sold; provided that, with respect to the first Sales Year for a Product Category, Sales Year means the period commencing on the date of First Commercial Launch of the first Product in such Product Category and ending on the last day of the fourth full Calendar Quarter after such First Commercial Launch (the “First Sales Year”), and for subsequent Sales Years for such Product, the period of four (4) sequential Calendar Quarters commencing on the day after the expiration of the First Sales Year or the anniversary thereof.

1.82 “Senior Executive”. Senior Executive means, with respect to Adamas, the Chief Executive Officer of Adamas or his or her designee, and, with respect to Forest, the Senior Vice President for Corporate Development of Forest Parent or his or her designee.

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1.83 “Sublicensee”. Sublicensee means a Third Party that has been granted a right or sublicense by Forest, its Affiliates or (sub)licensees under the rights and licenses granted or assigned to Forest pursuant to Section 2.1 of this Agreement or other rights and licenses pertaining to an FDC Product, which rights include at least rights to sell or otherwise Commercialize a Product (including an Authorized Generic). Third Parties that are permitted only to (a) distribute and resell a Product, or (b) Manufacture a Product solely for supply to Forest (or its Affiliates or its Sublicensees) (and have no other rights to Develop or Commercialize such Product) are not “Sublicensees”. [*] and its Affiliates shall not be considered Sublicensees of Forest or any of its Affiliates as a result of the rights granted to [*] under the [*] Agreements as existing as of the Effective Date, but [*] and its Affiliates shall be deemed Sublicensees of Forest in the event Forest, or any of its Affiliates, grants to [*] a sublicense under the license granted to Forest under Section 2.1.

1.84 “Sublicensing Revenue”. Sublicensing Revenue means any cash payment (including upfront fees, milestone payments and royalties) or the fair market value of any other consideration received [*] in consideration for or otherwise based upon a Transaction. Notwithstanding the foregoing, Sublicensing Revenues shall exclude all amounts received as bona fide consideration: (a) with respect to any [*]; (b) as loans [*], and solely for so long as such obligation of repayment exists; (c) in consideration of any issuance of equity or debt securities [*], except to the extent that such payments are in excess of fair market value for such securities (in which case such excess shall be deemed Sublicensing Revenue); (d) as reimbursement of costs and expenses incurred [*] (except to the extent such amounts exceed market rates, in which case such excess shall be deemed Sublicensing Revenue); (e) for the supply of Products or other materials (except to the extent that such payments exceed the cost of supplying such Products plus a customary margin, in which case such excess shall be deemed Sublicensing Revenue); or (f) in consideration for a Change of Control of Adamas; and shall be net of all withholding taxes or other amounts withheld or deducted from the amounts received [*], provided that if [*] withholding taxes or other such amounts withheld or deducted from the amounts received [*], the amount of any such benefit shall be included in Sublicensing Revenue.

1.85 “Territory”. Territory means the United States of America (including its territorial possessions, territories and the Commonwealth of Puerto Rico).

1.86 “Third Party”. Third Party means any Person other than Adamas or Forest or any of their respective Affiliates.

1.87 “Trademark Rights”. Trademark Rights means any word, name, symbol, color, shape, designation or device or any combination thereof, including any trademark, service mark, trade name, trade dress, brand name, product configuration, logo, design or business symbol, that functions as an identifier of source, origin, membership, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.88 “US”. US means the United States of America (including its territorial possessions, territories and the Commonwealth of Puerto Rico).

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1.89 “Valid Claim”. Valid Claim means any claim from an issued and unexpired patent that has not been revoked or held unenforceable or invalid by a final decision of a court or other Governmental Authority of competent jurisdiction, or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

1.90 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

<u>Definition:</u>	<u>Section:</u>
Acceptance Milestone	Section 6.3(a)(iii)
Acquirer	Section 1.20
[*]	Section 2.5
[*]	Section 1.62
Adamas	Preamble
[*]	Section 6.4(d)(iv)
Adamas FDC and ER Patent Rights	Schedule 11.6
Adamas FDC Patent Rights	Schedule 11.6
Adamas IP Infringement Claim	Section 7.4(a)

Adamas Manufacturing Know-How	Section 3.1(c)
Adamas Paragraph IV Claim	Section 7.11(a)
Adamas Patent Challenge	Section 7.3(d)(ii)
[*]	Section 6.4(d)(iv)
Agents	Section 8.1
Alliance Manager	Section 4.2(c)
Antitrust Action	Section 11.2(c)
Antitrust Law	Section 11.2(c)
Approval Milestone	Section 6.3(a)(iv)
Arbitrators	Section 12.2(b)(i)
Assignment and Assumption Agreement	Section 2.7
Bayh-Dole Act	Section 9.1(l)
Bioequivalence Milestone	Section 6.3(a)(i)
Cessation Notice	Section 11.2(a)
Claim	Section 12.2(b)(i)
Confidential Information	Section 8.2
Confidentiality Agreement	Section 8.2
Courts	Section 12.1
[*]	Section 3.3
Effective Date	Preamble
ER Royalty Term	Section 6.4(c)(iii)
Existing Supply Agreement	Section 3.3
FDC Launch Assumptions	Section 5.4
FDC Royalty Term	Section 6.4(c)(i)
First Sales Year	Section 1.81
Forest	Preamble
Forest Blocking Patent	Section 6.4(c)(vii)

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Definition:	Section:
[*]	Section 9.2(e)
Forest Parent	Preamble
Forest Parties	Section 10.2
Forest Patent Challenge	Section 7.3(b)
Forest Reversion Intellectual Property	Schedule 11.6
Forest Third Party Patent Licenses	Section 6.4(c)(vii)
Indemnified Party	Section 10.3(a)
Indemnifying Party	Section 10.3(a)
Initial Development Plan	Section 1.25
Invalidity Claim	Section 7.5
JAMS	Section 12.2(b)(i)
JDC	Section 4.1
Joint IP Working Group; JIPWG	Section 7.1
Joint Know-How	Section 7.2
Joint Manufacture Committee; JMC	Section 3.3
Joint Patent Rights	Section 7.2
Late Payment Notice	Section 6.9
[*]	Section 5.4
Letter Agreement	Section 4.2(a)
[*]	Section 6.4(d)(iii)
Milestone Event	Section 6.3(a)
Milestone Payment	Section 6.3(a)
[*]	Section 1.62
Outside Milestone Date	Section 6.3(b)

Paragraph IV Claim	Section 7.11(a)
Payment Date	Section 2.1(b)
Pre-Change of Control Rights	Section 1.20
[*]	Section 2.5
Primary Detail	Section 1.23
Product Category	Section 1.81
Proprietary Non-Donepezil FDC Product	Section 6.4(c)(ii)
Proprietary Non-Donepezil FDC Royalty Term	Section 6.4(c)(ii)
Regulatory Filings	Section 2.6
Regulatory Plan	Section 1.80
Regulatory Plan Change	Section 4.2(d)(ii)
Related Adamas Patent Rights	Section 1.8
Reverted FDC Products	Schedule 11.6
Royalty Commencement Date	Section 6.4(c)(iv)
Rules	Section 12.2(b)(i)
Secondary Detail	Section 1.23
Stability Milestone	Section 6.3(a)(ii)
Technology Transfer Plan	Section 3.1(a)

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Definition:**Section:**

Term	Section 11.1
Termination Effective Date	Schedule 11.6
Third Party Claims	Section 10.1
Third Party Infringement Claims	Section 7.7
Third Party Technology	Section 2.1(d)
Transaction	Section 6.4(d)(i)
Transferable Contracts	Section 2.7
Triggering Act	Section 6.4(d)(i)

1.91 Captions; Certain Conventions; Construction. All headings and captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires:

- (a) words of any gender include each other gender;
- (b) words such as “herein”, “hereof” and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear;
- (c) words using the singular shall include the plural, and vice versa;
- (d) the words “include,” “includes” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation”, “inter alia” or words of similar import;
- (e) the word “or” shall be deemed to include the word “and” (*i.e.*, shall mean “and/or”);
- (f) references to “Article,” “Section,” “Exhibit,” “subsection”, “paragraph”, “clause” or other subdivision, or to a Schedule, without reference to a document, are to the specified provision or Schedule or Exhibit of this Agreement;
- (g) references to “\$” or “dollars” shall be references to US Dollars; and
- (h) the phrase “have the right” means “have the right, without the obligation”, unless expressly stated otherwise.

This Agreement shall be construed as if the Parties drafted it jointly.

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ARTICLE II

GRANTS OF RIGHTS

2.1 Grants of Rights.

(a) License Grant by Adamas.

(i) Adamas hereby grants, on behalf of itself and its Affiliates, to Forest (A) a co-exclusive (with Adamas and its Affiliates) right and license under the Adamas Intellectual Property to Develop and Manufacture Products in the Field in the Territory in accordance with Articles III and IV, (B) an exclusive (even as to Adamas and its Affiliates) right and license under the Adamas Intellectual Property to Commercialize Products in the Field in the Territory in accordance with Article V, and (C) a non-exclusive right and license under the Adamas Ex-US Patent Rights and Adamas Know-How to Develop and Manufacture (but not sell or otherwise Commercialize) Products in the Field outside the Territory in accordance with Articles III and IV solely in support of the Development or Commercialization of the Products in the Field in the Territory. Notwithstanding the foregoing, Adamas shall retain rights under the Adamas Intellectual Property and the Adamas Ex-US Patent Rights (X) to Develop Products in the Field in the Territory in accordance with Article IV, and (Y) to Develop and Manufacture the Products anywhere in the world solely in support of the Development or Commercialization of the Products outside the Territory.

(ii) Adamas hereby grants, on behalf of itself and its Affiliates, to Forest (A) an exclusive (even as to Adamas and its Affiliates), non-royalty-bearing right and license, to use the Adamas Product Trademark Rights in connection with the Development, Manufacture and Commercialization of the Products in the Field in the Territory in accordance with this Agreement and (B) a non-exclusive, non-royalty-bearing right and license to use the Adamas Product Trademark Rights to Develop and Manufacture the Products in the Field outside the Territory in accordance with this Agreement in support of the Development or Commercialization of the Products in the Field in the Territory. Notwithstanding the foregoing, Adamas shall retain a non-exclusive, non-royalty-bearing right to use the Adamas Product Trademark Rights (X) to Develop Products in the Field in the Territory in accordance with Article IV, and (Y) to Develop and Manufacture the Products anywhere in the world in support of the Development or Commercialization of the Products outside the Territory. In the event that Forest elects to use an Adamas Product Trademark Right in the Development, Manufacture or Commercialization of a Product, the Parties shall coordinate the use of domain names incorporating such Adamas Product Trademark Right so as to avoid confusion in the Commercialization of such Product in the Territory and outside the Territory. For clarity, Adamas shall retain all right, title and interest in and to the domain names within the Adamas Product Trademark Rights for country-specific domains outside of the Territory (e.g., .uk, .jp, .eu), while Forest shall be granted rights under this Section 2.1(a)(ii) to the domain names within the Adamas Product Trademark Rights in the Territory (e.g., .com, .net, .org). If elected by Forest at any time, Forest shall have the right to terminate the rights and licenses granted by Adamas to Forest under this Section 2.1(a)(ii) upon written notice to Adamas, in which case all rights to the Adamas Product Trademark Rights granted to Forest under this Agreement shall revert to Adamas, in which case Adamas agrees not to use the Adamas Product Trademark Rights in the Territory.

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(iii) Adamas hereby grants, on behalf of itself and its Affiliates, to Forest a non-exclusive, non-royalty-bearing right and license to use the corporate names of Adamas and its Affiliates as required by Law or as otherwise reasonably required in connection with the performance of Forest's obligations or exercise of its rights hereunder.

(iv) Sublicenses. Forest shall have the right to grant sublicenses through multiple tiers under the licenses to Adamas Intellectual Property and the Adamas Product Trademark Rights granted to Forest under this Section 2.1(a) to its Affiliates and, [*], to Third Parties [*], provided that Forest shall not have the right to grant a sublicense [*] unless [*].

(b) Payment Date; Forest's Election to [*]. Upon payment by Forest or its designee to Adamas of all Milestone Payments that have or may come due under Section 6.3 (the date Adamas receives the last of such payments, the "Payment Date"), Forest shall have the right (but not the obligation) to request that [*] and [*] and [*] and [*], and Forest shall make such request by providing written notification to Adamas thereof within [*] after the Payment Date. In the event Adamas receives such written notification from Forest within [*] after the Payment Date, Adamas shall: (i) promptly [*] within [*] of receipt of written notification from Forest requesting [*]; and (ii) cooperate fully with Forest [*] or [*] and [*] as contemplated in this Section 2.1(b), including [*]. For any [*] and [*] (either [*] or [*], or [*]), the [*] shall [*] following the Payment Date and [*].

(c) Possible License from Forest. In the event Forest requests that Adamas perform any Development activities under this Agreement that would require a license to any Patent Rights, Know-How or Trademark Rights Controlled by Forest or its Affiliates, Forest agrees that Forest shall grant Adamas a non-exclusive, royalty-free license under the relevant Patent Rights, Know-How or Trademark Rights Controlled by Forest or its Affiliates, in each case, that are necessary for Adamas to perform the activities requested to be performed under this Agreement solely for such purpose.

(d) Third Party Technology. With respect to any Patent Rights or Know-How that Adamas or its Affiliate acquires from a Third Party (by license or otherwise) after the Effective Date that would be subject to a license granted to Forest pursuant to this Section 2.1 (collectively, "Third Party Technology"), Adamas shall promptly notify Forest in writing of such Third Party Technology, the associated obligations applicable to Forest (including payment obligations that would be triggered by Forest's exercise of the rights and licenses granted to it under this Section 2.1). Such Third Party Technology shall be included in the Adamas Patent Rights (including the Adamas Memantine Patent Rights, if applicable), Adamas Know-How, and Adamas Intellectual Property, provided that, subject to Section 6.4(c)(vii), Forest shall be responsible for any obligations applicable to Forest under the applicable agreement (including any payment owed to such Third Party by Adamas or its Affiliate that would be triggered by Forest's exercise of the rights and licenses granted to it under this Section 2.1). With respect to Article VII, Forest may exercise the rights set forth in Article VII with respect to such Third Party Technology to the extent consistent with the terms and conditions of the license agreement pursuant to which Adamas or its Affiliate first acquired rights to such Third Party Technology. If Forest has a reimbursement obligation under this Section 2.1(d), Adamas shall provide Forest with documentation of Forest's reimbursement obligations under this Section 2.1(d) and Forest

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shall pay any such amounts owed within [*] of receipt thereof. Forest may [*] Third Party Technology acquired by Adamas or its Affiliate [*] Adamas thereof at any time [*]; upon [*], such Third Party Technology [*]. For clarity, Forest shall be responsible for any above described payment owed to the Third Party by Adamas or its Affiliate for such Third Party Technology accruing [*] under this Section 2.1.

2.2 Rights Retained by the Parties. Any rights of Adamas or Forest (or their respective Affiliates), as the case may be, not expressly granted to the other Party under the provisions of this Agreement shall be retained by such Party, and no right or license, other than those expressly granted hereunder, under either Party's Know-How, Patent Rights or other subject matter is granted or shall be deemed granted by implication or estoppel. Notwithstanding any provision to the contrary herein, no right or license is granted to either Party herein with respect to, and none of the Forest Intellectual Property, the Forest Reversion Intellectual Property and the Adamas Intellectual Property shall include any Patent Rights or Know-How to the extent specifically Covering or solely relating to, any active ingredients other than (a) Memantine, (b) Donepezil (including the Donepezil [*]) for use in an FDC Product, or (c) Memantine and Donepezil (or Donepezil [*]) in combination with one another.

2.3 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under Section 2.1 to Patent Rights and Know-How (including any data included in the Know-How), are and will otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Each Party will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against the licensor Party under the Bankruptcy Code or analogous provisions of applicable Law outside the United States, the licensee Party will be entitled to a complete duplicate of (or complete access to, as the licensee Party deems appropriate) such intellectual property and all embodiments of such intellectual property, which, if not already in the licensee Party's possession, will be promptly delivered to it upon the licensee Party's written request thereof. Any

agreements supplemental hereto will be deemed to be “agreements supplementary to” this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

2.4 Exclusivity; Change of Control.

(a) Exclusivity. During the Term, subject to Section 2.4(b) below, neither Adamas nor any of its Affiliates shall, alone or in collaboration with any other Person, Commercialize any Product in the Field in the Territory, or grant a license to any other Person to Commercialize any Product in the Field in the Territory; provided, however, that neither this clause (a) (nor any other provision of this Agreement) shall preclude Adamas or its Affiliates from [*] that [*], [*] and [*], if Adamas or such Affiliate has the legal right to do so.

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2.5 Change of Control. Notwithstanding anything herein to the contrary, in the event of a Change of Control of Adamas, the Acquirer of Adamas shall not be deemed to be in breach of Section 2.42.4(a) with respect to any Product that an Acquirer is Developing or Commercializing at the time of the closing or consummation of such Change of Control or thereafter Develops or Commercializes; provided, that (i) any Development and Commercialization was or is conducted without a license (or under or in connection with a Pre-Existing Adamas License) under any Adamas Patent Right or Adamas Know-How and without use of any Confidential Information within the Adamas Know-How (unless such use is unintentional, immaterial and inconsequential) or any Confidential Information of Forest disclosed to Adamas under this Agreement, and (ii) the Acquirer does not use, reference or rely on any Regulatory Filings that are assignable or assigned to Forest hereunder (including any IND transferred to Forest) or any IND or Regulatory Approval held by Forest, in each case of (i) and (ii), to Develop, Manufacture or Commercialize such Acquirer’s Products (any such Products, for so long as such conditions are met, “Acquirer Products”). In addition, if rights to Adamas Intellectual Property were granted to the Acquirer prior to the Change of Control, then the use and practice of such Adamas Intellectual Property, in accordance with such grant (and consistent with the exclusive licenses granted under this Agreement) shall not cause any Product to be excluded from the definition of Acquirer Products pursuant to the foregoing; provided that such rights to Adamas Intellectual Property were granted in a separate transaction prior to the Change of Control that would permit exercise of the licenses even in the absence of the Change of Control and were not granted immediately preceding the Change of Control or in order to exempt the Acquirer Products from the provisions of this Section 2.4 (“Pre-Existing Adamas License”). Acquirer Products shall not be subject to the royalty obligations set forth in Section 6.4. If at any time, any of the foregoing conditions ((i) and (ii)) are not met with respect to a Product, then such Product shall automatically and thereafter no longer be considered an Acquirer Product and the exemption from Sections 2.42.4(a) and 6.4 afforded by this Section 2.42.5 shall no longer apply with respect to such Product.

2.6 Ownership of Regulatory Filings; Transfer of Regulatory Filings. As soon as practicable following the Effective Date, Adamas shall (a) assign and transfer to Forest all INDs and other filings with Regulatory Authorities in the Territory (such filings, the “Regulatory Filings”) pertaining to any Product in the Field that are Controlled by Adamas or its Affiliates as of such date and (b) deliver to Forest copies of all such Regulatory Filings, including copies of all correspondence with Regulatory Authorities and all written minutes of meetings and memoranda of conversations with Regulatory Authorities, in each case, relating thereto and not previously provided to Forest or its Affiliate. [*]. Forest shall, as between the Parties, be the owner of all Regulatory Filings (including all INDs) in the Territory for the Products in the Field, provided that Adamas shall have the right to file and own its own IND in the Territory for the Products in connection with the Development of the Product in the Territory by Adamas, its Affiliates or (sub)licensees solely to support the Commercialization of the Products outside the Territory. The exchange of safety information between the Parties relating to the Development of Products in the Territory carried out by each Party under its own Regulatory Filings will be subject to the provisions of Section 4.5.

2.7 Assignment of Contracts. As soon as practicable following the Effective Date, Adamas shall assign to Forest those written agreements by and between Adamas and Third

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Parties set forth on Schedule 2.6 (the “Transferable Contracts”) that Forest explicitly requests to be assigned to Forest, pursuant to an assignment and assumption agreement to be agreed by the Parties (the “Assignment and Assumption Agreement”); provided that Forest shall make such request within [*] after the Effective Date. With respect to any Transferable Contract not promptly assigned to Forest under this Section 2.7, the Parties shall coordinate to ensure that Forest obtains the benefits under such contracts as reasonably necessary or useful to perform the Development activities contemplated to be performed by Forest hereunder in a manner consistent with such contracts or to facilitate an agreement directly between Forest and the other party to such Transferable Contract providing such benefits, and [*]. This Agreement does not constitute an agreement to assign or transfer any Transferable Contract that is not assignable or transferable without the consent of or action by a Third Party or action by a Governmental Authority, to the extent that such consent has not been given or such action has not been taken prior to the Effective Date; provided, however, that Adamas shall, and shall cause its Affiliates to, use Commercially Reasonable Efforts to obtain, and Forest shall assist and cooperate with Adamas in connection therewith, all necessary consents to the assignment and transfer thereof. Subject to Section 3.3, Forest shall not be responsible for any obligations under any Adamas contracts with Third Parties related to the Development or Manufacture of Products, other than the Transferable Contracts that are assigned or transferred to Forest pursuant to this Section 2.7 and, with respect to such Transferable Contracts, Forest shall only be responsible for costs incurred by Forest under the Transferable Contracts after the Effective Date or otherwise as expressly set forth in this Agreement or the Assignment and Assumption Agreement. From and after the Effective Date until the assignment of a Transferable Contract to Forest pursuant to this Section 2.6, Adamas shall [*] such Transferable Contract [*].

ARTICLE III MANUFACTURING AND TECH TRANSFER

3.1 Transfer of Adamas Know-How.

(a) Initial Transfer of Adamas Know-How. In order to fully enable Forest to practice the Adamas Know-How with respect to Products in accordance with this Agreement and to otherwise exercise the rights granted to it under this Agreement, Adamas shall promptly deliver to Forest as further set forth below copies of Adamas Know-How existing in written form, including copies of any relevant portions of documents, files, diagrams, specifications, designs, schematics, reports, records, laboratory notebooks, data, and other written or graphic material, in the media and form that such material exists in Adamas’ Control as of the Effective Date to the extent that any such item [*] to disclose or embody Adamas Know-How, to the extent not previously provided to Forest. Without limiting the foregoing, Adamas shall deliver to Forest copies of all correspondence filed with or received from the United States Patent and Trademark Office in connection with the prosecution of the Adamas Memantine Patent Rights that are in Adamas’ Control promptly after the Effective Date and in a timely manner [*]. Notwithstanding the foregoing, Adamas shall not be obligated to transfer to Forest any quantities of GMP-grade materials other than pursuant to Section 3.2 below. The content and mode of transfers of Adamas Know-How to Forest shall be conducted, in accordance with this Section 3.1 and a technology transfer plan and budget to be reasonably agreed by the Parties within [*] of the Effective Date (the “Technology Transfer Plan”), within [*] after the Effective Date (and

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Adamas’ obligations under this Section 3.1 apply whether or not a Technology Transfer Plan is agreed). Without limitation to the foregoing, with respect to the Adamas Know-How related to Memantine-Donpezil FDC Products, the Parties shall coordinate any such transfer of Adamas Know-How to enable each Party to carry out the Development activities with respect to the Development of Memantine-Donpezil FDC Products assigned to such Party under the Development Plan. The foregoing transfers of Adamas Know-How to Forest shall [*]. Without limitation of the foregoing, during such [*] period, Adamas shall deliver to Forest copies of all Adamas Know-How [*] as of the Effective Date, including copies of any relevant portions of the documents, files and other written or graphic materials disclosing or embodying Adamas Know-How specified to be transferred to Forest during such [*] period as agreed pursuant to the Technology Transfer Plan, if any, to the extent not previously provided to Forest, and shall make employees of Adamas who are familiar with such Adamas Know-How reasonably available to [*] in accordance with the Technology Transfer Plan. Adamas’ failure to deliver to Forest [*] in the Adamas Know-How (i.e., [*]) during such [*] period shall not constitute a breach of this Agreement if Adamas delivers such document to Forest promptly following Adamas’ becoming aware of the omission.

(b) Additional Transfer of Adamas Know-How. In the event that Forest desires additional transfer assistance from Adamas beyond the [*] period set forth in Section 3.1(a) (though this period of additional assistance shall last only until [*]), upon Forest’s reasonable request or as new Adamas Know-How becomes available, Adamas shall deliver to Forest [*] or as reasonably requested by Forest all Adamas Know-How, and Adamas shall [*] Adamas [*] Adamas Know-How [*] at such times,

and in the case of [*], to be agreed upon by the Parties as reasonably necessary [*] to transfer such Adamas Know-How to Forest to enable Forest to understand and implement the Adamas Know-How with respect to the Products in accordance with this Agreement. In addition, promptly after [*], Adamas shall deliver to Forest copies of all [*] (including [*]) to the extent not previously provided to Forest. Forest shall [*].

(c) Transfer of Adamas Manufacturing Know-How. Specifically without limiting the foregoing, upon Forest's request, Adamas shall transfer or arrange for the transfer to Forest: (i) the Adamas Donepezil Formulation existing as of the Effective Date; (ii) the then-current Manufacturing process Controlled by Adamas that is necessary to enable Forest to Manufacture [*]; (iii) the formulation and then-current Manufacturing process Controlled by Adamas for the Manufacturing of [*]; and (iv) the then-current Manufacturing process for [*] (collectively, the "Adamas Manufacturing Know-How"). The Adamas Manufacturing Know-How shall be deemed Adamas Know-How under this Agreement. Forest shall reimburse Adamas for Adamas' FTE Costs and any reasonable, documented, out-of-pocket costs, in each case incurred directly in connection with the technology transfer in accordance with this Section 3.1(c).

(d) Confidentiality of Adamas Know-How. Forest expressly acknowledges and agrees that Adamas Know-How shall remain Adamas' Confidential Information throughout the Term (unless any of Section 8.2(a) through (d) apply), and the use and disclosure of such Confidential Information shall be governed under the terms and conditions of Article VIII hereunder. Specifically and without limiting the foregoing, Forest shall not disclose any Adamas

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Know-How: (i) [*] unless and only to the extent [*]; or (ii) to any other Third Party except solely in furtherance of the Development, Manufacture and Commercialization of the Products in the Territory under this Agreement on behalf of Forest, its Affiliates and Sublicensees, in each case of (i) and (ii), only if such disclosure is under written confidentiality and non-use obligations binding upon [*] recipient of any Adamas Know-How: (A) to prevent any further disclosure by [*] recipient of such Adamas Know-How; and (B) to restrict the use of such Adamas Know-How, [*] solely in furtherance of the Development, Manufacture and Commercialization of the Products in the Territory under this Agreement on behalf of Forest, its Affiliates and Sublicensees.

3.2 Supply of Donepezil [*]. Prior to the earlier of: (a) the [*] anniversary of the Effective Date, which such period shall be extended to the [*] anniversary of the Effective Date for so long as Forest is negotiating in good faith an agreement for the supply of Donepezil [*]; and (b) the assignment of the applicable Transferable Contracts relating to the Manufacture and supply of Donepezil [*] to Forest pursuant to Section 2.7, Adamas shall, upon Forest's reasonable request (including for any studies to be performed by Forest hereunder), obtain Donepezil [*] from the applicable Third Party supplier(s) and supply such Donepezil [*] to Forest for use in performing the Development Plan or any other use hereunder. Forest shall pay to Adamas [*] for such Donepezil [*]. Adamas shall not be liable with respect to such supply for amounts in excess of amounts that Adamas recovers from any such Third Party supplier with respect to any failure regarding such supply (to the extent caused by such Third Party supplier); provided that Adamas shall use reasonable efforts to recover any such amounts from such Third Party supplier(s).

3.3 Coordination of Certain Supply. Promptly after the Effective Date, the Parties shall establish a joint working group to oversee and coordinate the Parties' activities with respect to the supply of [*] for each Party's respective territory (the "Joint Manufacture Committee" or "JMC"), including coordination of supply, chemistry, manufacturing, and controls (CMC) information, and Third Party suppliers of [*] to the benefit of each Party. The JMC shall review and determine, [*] how to coordinate supply of the [*] either under existing arrangements with Third Party suppliers of [*] ("Existing Supply Agreements") or under new arrangements with such Third Party suppliers, in light of each Party's requirements in its respective territory. For clarity, the JMC shall not have the power to [*]. If the JMC determines to [*], or to otherwise [*] in a manner that would result in [*], or if [*] or otherwise [*], which [*] results in [*], then the Parties shall [*]. Notwithstanding the foregoing, the Parties agree to use good faith efforts to cooperate to [*].

3.4 Regulatory Inspection. In connection with a request from a Regulatory Authority related to obtaining and maintaining Regulatory Approval with respect to a Product, each Party shall permit the other Party, or an authorized representative of the other Party reasonably acceptable to such Party, to enter the relevant facilities of such Party and its Affiliates during normal business hours and upon reasonable advance notice to inspect and verify compliance with applicable regulatory and other requirements as well as with this Agreement, with respect to all matters relating to the Development of the Products under this Agreement. Each Party shall give the other Party or its authorized representative, all necessary and reasonable assistance for a full

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and correct carrying out of the inspection. Such inspection shall not relieve a Party of any of its obligations under this Agreement.

ARTICLE IV DEVELOPMENT

4.1 General. From and after the Effective Date, except as otherwise expressly provided in Section 2.1 above or this ARTICLE IV (or the Development Plan), Forest shall have the sole right to conduct Development of the Products in the Field in the Territory. Forest shall, directly or indirectly through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for a Memantine-Donepezil FDC Product in the Field in the Territory in accordance with the Development Plan and the Regulatory Plan, including the conduct of the DM303 and DM304 studies. In exercising such efforts, Forest shall first use the Initial FDC Product as the first FDC Product, unless it determines in good faith that: (a) [*] an alternative formulation of Donepezil; or (b) [*] an alternative formulation of Donepezil (or if [*]); or (c) [*] an alternative formulation of Donepezil instead of such Adamas Donepezil Formulation. If Forest desires to use an alternative formulation of Donepezil for one or more of the foregoing reasons, then prior to implementing such alternative formulation, Forest shall notify Adamas in writing and shall discuss in good faith with Adamas any such proposed change, and Forest shall consider in good faith any commercially reasonable proposal by Adamas for overcoming such reasons, prior to effecting any change in formulation; provided, however, that [*] an alternative formulation of Donepezil if [*] would [*] set forth in the Development Plan for the Development of the Memantine-Donepezil FDC Product. [*] or [*] or [*] under this Section 4.1, whether or not [*], shall be deemed an “Adamas Donepezil Formulation Modification.” Forest hereby represents and warrants that, as of the Effective Date, it is [*], and has [*] pertaining to, [*]. The Development of the Memantine-Donepezil FDC Products for Commercialization in the Field in the Territory (including all regulatory interactions with the FDA and the appointment of all contract research organizations engaged in connection with the Develop or Manufacture the Memantine-Donepezil FDC Products) shall be managed by a Joint Development Committee (the “JDC”), subject to the terms of this Agreement. Adamas and its Affiliates may not conduct Development of a Product in the Field in the Territory for Commercialization of such Product in the Field in the Territory except as explicitly set forth in this Agreement or as otherwise determined by the JDC. The conduct of Development of any Product for Commercialization in the Territory in the Field other than any Memantine-Donepezil FDC Product shall [*].

4.2 Development of the Memantine-Donepezil FDC Products.

(a) Joint Development Plan. All Development of the Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field shall be conducted in accordance with the Development Plan until the disbandment of the JDC in accordance with Section 4.2(b)(ii). The Development Plan shall set forth the activities to be performed by each Party with respect to the Development of the Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field. The Development Plan may be amended by the JDC from time to time in good faith and as reasonably necessary or useful for the Development of the Memantine-Donepezil FDC Products; provided that the JDC shall not [*] except [*] and the JDC shall not [*]. In the event that the Development Plan does not specify which Party

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shall be responsible for a particular Development activity, the JDC shall assign the activity to one of the Parties. Each Party shall act in a manner consistent with the Development Plan and with the Regulatory Plan. Forest shall, [*] in connection with the Development activities assigned to Adamas in the Development Plan, which Development activities shall include activities assigned to Adamas under a certain letter agreement between Adamas and Forest, dated [*] (the “Letter Agreement”). The following shall apply to Adamas’ activities under such Letter Agreement: (i) until [*] the cessation of any ongoing activities under the Letter Agreement, Adamas shall continue to conduct such activities; (ii) such activities are deemed to be conducted under the Development Plan and subject to the foregoing reimbursement by Forest to Adamas; and (iii) such reimbursed amounts shall consist of: (A) the amounts consistent with the budget set forth in the Letter Agreement; (B) the amounts incurred by or on account of Adamas [*] with respect to such activities; and (C) the amounts incurred by Adamas for its FTEs and consultants as required to support the activities set forth in

subsection (A) and/or (B) above; provided, however, that any amounts in (B) or (C) shall be only for activities specifically requested by Forest, and the Parties shall cooperate in good faith to agree on a written budget therefor within [*] Business Days after the Effective Date. If Adamas is assigned any activities other than those set forth in the Letter Agreement, the Parties shall agree in advance to a budget and such expenses shall be reimbursable to the extent consistent with the budget. If [*] or [*] the activities assigned to Adamas under this Section 4.2(a) (including the activities described in the Letter Agreement), Adamas shall [*]. Each Party shall conduct or cause to be conducted all activities assigned to it under the Development Plan in accordance with applicable Law and best industry practices.

(b) Joint Development Committee. The Parties hereby establish the JDC to oversee and coordinate the Parties' activities with respect to the Development of the Memantine-Donepezil FDC Product in the Field in the Territory as follows:

(i) Composition of the Joint Development Committee; Decision Making. The Development Plan activities shall be conducted under the oversight of the JDC comprised of three (3) named senior representatives of Forest and three (3) named senior representatives of Adamas. Each Party shall notify the other within [*] after the Effective Date of the appointment of its representatives to the JDC. Each Party may change its representatives to the JDC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with Development Plan activities as well as sufficient authority to take actions on behalf of a Party to the extent permitted under this Agreement. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JDC meetings. Alliance Managers shall be invited to attend all JDC meetings. The JDC shall be chaired [*]. Each Party shall have collectively one (1) vote in all decisions and the Parties shall attempt to make decisions by consensus. In the event the JDC cannot reach consensus on any matter within the scope of its oversight, disputes shall be referred to the Parties' respective Senior Executives. If the Senior Executives cannot resolve the dispute within [*] after the dispute has been referred to them, then Forest shall have the final decision-making

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authority with respect to such dispute, except that Forest shall not have any final decision-making authority with respect to [*] or [*], any dispute with respect to which shall be [*]. Notwithstanding the foregoing, Forest shall not exercise such final decision-making authority in any manner that (A) [*] unless [*] and [*], or (B) is inconsistent with this Agreement. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.

(ii) Meetings; Disbandment. [*], the JDC shall meet in accordance with a schedule established by mutual written agreement of the JDC representatives, but no less frequently than [*] unless otherwise agreed by the Parties. The location for meetings of the JDC shall alternate between Adamas and Forest facilities in the US (or such other location as may be agreed by the Parties). Alternatively, the JDC may meet by means of teleconference, videoconference or other similar communications equipment. [*], or [*], the JDC shall disband [*] the Development of the Memantine-Donepezil FDC Products for Commercialization in the Field in the Territory, in accordance with the terms and conditions of this Agreement.

(iii) Scope of Joint Development Committee Oversight. The JDC's oversight responsibilities shall be limited to the Development of the Memantine-Donepezil FDC Products in the Field for Commercialization in the Territory. Within such scope and subject to the other provisions of this Section 4.2, the JDC may take any action reasonably necessary for the Development of the Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field (including obtaining Regulatory Approval therefor) in accordance with this Agreement. Such actions may include, but are not limited to (A) conferring regarding the status of Development Plan activities; (B) reviewing and approving amendments to the Development Plan; (C) approving any contract research organization or other service provider engaged by Adamas to Develop Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field, to the extent such entities are not so engaged prior to the Effective Date; (D) establishing any changes to the Regulatory Plan for the Development of Memantine-Donepezil FDC Products in accordance with Section 4.2(d); (E) establishing guidelines and strategies for publications involving Products; and (F) addressing such other matters relating to the Development of Memantine-Donepezil FDC Products in the Field for Commercialization in the Territory in the Field as are specified in this Agreement to be brought before the JDC. Each Party shall keep the JDC informed as to its activities under the Development Plan, but shall have the right to make day-to-day operational decisions in performing activities assigned to it under the Development Plan, provided that those decisions are not contrary to the Development Plan and that any protocols for studies to be conducted under the Development Plan shall be subject to review and approval of the JDC. Notwithstanding anything to the contrary in this Agreement, the JDC shall have no authority to (X) determine [*], (Y) make any decision expressly allocated herein to either or

both Parties, or (Z) amend or interpret any provision of this Agreement, other than the Development Plan pursuant and subject to this Section 4.2.

(c) Alliance Managers. In addition to the JDC, Adamas and Forest each acknowledge and agree that it would be beneficial to each to have a representative with a general understanding of the Development, Manufacturing and Commercialization issues relating to Memantine-Donepezil FDC Products to act as an alliance manager ("Alliance Manager") and shall appoint such a person promptly after the Effective Date. It is envisioned that the Alliance Managers will serve as a single point of contact within each Party with responsibility for facilitating communication and collaboration between the Parties hereunder. The Alliance

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Managers shall work together to manage and facilitate the resolution (in accordance with the terms of this Agreement) of business issues between the Parties that arise in connection with this Agreement.

(d) Regulatory Plan.

(i) The Parties acknowledge that the Regulatory Plan is based upon the Development of the Memantine-Donepezil FDC Product as contemplated in the End of Phase II Meeting Minutes to support an initial NDA and a supplemental NDA for such Memantine-Donepezil FDC Product, and the Parties intend to conduct the Initial Development Plan, using the efforts specified in Section 4.1, to submit an initial NDA and supplemental NDA based upon the results of such conduct of the Initial Development Plan.

(ii) In the event that the FDA requires (as evidenced in writing, or as would reasonably be interpreted by a sponsor of a Regulatory Filing (in the latter case including by reason of the progress or results of the Development Plan activities in light of applicable FDA standards)) any modification to the Regulatory Plan that would result in an increase in the number of pre-clinical or clinical studies (excluding any additional stability study(ies)), an increase in the size of clinical studies or a change in the type of pre-clinical or clinical studies or a material change to the protocol for a clinical study for the Memantine-Donepezil FDC Product (excluding any change in duration of a stability study), as compared with the Regulatory Plan in existence as of the Effective Date (a "Regulatory Plan Change"), the JDC may amend the Regulatory Plan accordingly in good faith and as reasonably necessary to support obtaining Regulatory Approval for such Memantine-Donepezil FDC Product. In the event any Regulatory Plan Change requires results of any Development activity, other than the activities contemplated in the Initial Development Plan, for the submission of an NDA for such Memantine-Donepezil FDC Product, the JDC shall establish an update to the Development Plan, including a timeline to conduct such additional activity.

(iii) In addition to a Regulatory Plan Change, Forest may amend the Regulatory Plan in good faith and as reasonably necessary to support obtaining Regulatory Approval for such Memantine-Donepezil FDC Product; provided that [*] (A) such amendment by Forest (unless it results from a Regulatory Plan Change) or (B) [*], in each case ((A) or (B)) shall [*].

(e) Regulatory Responsibilities.

(i) Generally. The Parties' joint regulatory strategy with respect to the Development of the Memantine-Donepezil FDC Products for Commercialization in the Field in the Territory is as specified in the Regulatory Plan and further detailed in the Development Plan. Notwithstanding anything to the contrary in this Section 4.2(e), [*] all substantive submissions and communications made to Regulatory Authorities in the Territory (including the FDA) with respect to any Memantine-Donepezil FDC Product shall be subject to the prior approval of the JDC in writing and shall be provided to the JDC at least [*] (or less time as may be required by Regulatory Authorities in the Territory) prior to the intended date of submission or communication.

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(ii) Interaction with Regulatory Authorities. Forest shall be responsible for [*] (subject to the oversight of the JDC [*]), interactions with Regulatory Authorities in the Territory (including the FDA) with respect to the Development of the Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field. Notwithstanding the foregoing, [*], Forest shall promptly provide Adamas with prior written or email notice of all meetings, conferences and discussions scheduled with the FDA concerning all Memantine-Donepezil FDC Products (including advisory committee meetings and any other meeting of experts convened with the FDA concerning the Memantine-Donepezil FDC Products) within [*] after Forest or its Affiliate first receives notice of the scheduling of such meeting, conference or discussion (or within such shorter period as may be practicable and necessary in order to give Adamas a reasonable opportunity to attend such meetings, conferences and discussions). Adamas shall be entitled to have representatives of Adamas (or its Affiliates) with appropriate expertise [*] at all such meetings, conferences or discussions with the FDA relating to Memantine-Donepezil FDC Products, which at a minimum shall mean that Adamas and its Affiliates shall have the right to have [*]. Forest shall provide Adamas with reasonable advance notice, as set forth above, of all such meeting, conferences or discussions with the FDA and advance copies of all substantive submissions and written communications to the FDA in advance of such meetings, conferences or discussions, as well as any written correspondence received by Forest from the FDA with respect to such meetings, conferences or discussions. Forest shall promptly forward to Adamas copies of all minutes thereof and summaries of all such meetings, conferences and discussions with the FDA, including copies of all contact reports produced by or on behalf of Forest or its Affiliates. Forest shall consider in good faith Adamas' reasonable proposals or comments to any substantive submissions or communications made by Forest to Regulatory Authorities in the Territory (including the FDA) with respect to the Development of Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field [*] Adamas' proposal or comments with respect to any such submissions or communications made by Forest to Regulatory Authorities in the Territory.

(f) Exchange of Information Regarding Development; Use of Program Data. Each Party shall provide the other Party, at each meeting of the JDC until the JDC is disbanded in accordance with Section 4.2(b)(ii), with all material information and data relating to its Development of Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field. In addition, from time to time, each Party shall provide to the other Party all material information and data relating to such Party's Development of Memantine-Donepezil FDC Products for Commercialization in the Territory in the Field upon the other Party's reasonable request. In addition to its rights under and pursuant to Section 4.5, Adamas shall have the right to use such information received from Forest or its Affiliates to comply with all applicable Laws, including requirements by Regulatory Authorities. However, without limiting its rights under and pursuant to Section 4.5, Adamas shall not have the right to use any Program Data (i) in a manner that would [*], without [*] (including any [*] in connection therewith) or (ii) in support of any Regulatory Approvals in the Field in the Territory; provided, however, that Adamas shall have the right to use Program Data for such purpose in clause (ii) in a manner consistent with this Agreement if [*] and [*]. Nothing in this Section 4.2(f) shall be construed as an implied license to any intellectual property rights of Forest, its Affiliates or any Third Party. As and to the extent set forth in Section [*], the use of Program Data to support

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Regulatory Approval or Commercialization of any Product [*] shall [*] with respect to such Product.

4.3 Development of Other Products. As between the Parties, Forest shall have the sole right, at its sole cost and expense, to Develop Products other than the Memantine-Donepezil FDC Products for Commercialization in the Field in the Territory. The Development of such Products in the Field in the Territory shall [*]. All interactions with Regulatory Authorities in the Territory, including the FDA, with respect to any Product in the Field of Forest or its Affiliates other than Memantine-Donepezil FDC Products in the Field shall [*].

4.4 Avoiding Conflicting Development Activities.

(a) Prohibition. Each Party shall not, and shall cause its Affiliates to not, and shall use Commercially Reasonable Efforts to cause each of its and its Affiliates' licensees and (sub)licensees to not, conduct any Development activity regarding the Products that could reasonably be expected to result in a material adverse impact on the Development or Commercialization of the Products in the other Party's respective Major Market(s) (*i.e.*, in the case of Forest, with respect to a Product in the Field in the United States, and in the case of Adamas, with respect to a Product in the Field in Japan, the United Kingdom, France, Germany, Spain or Italy); provided that [*] shall not be deemed itself to be a material adverse impact on such Development or Commercialization of the Products. Each Party shall require each of its and its Affiliates' (sub)licensees that are conducting Development of Products to be subject to the provisions of this Section 4.4(a) (or analogous provisions with substantially the same terms set forth in this Section 4.4(a)). Notwithstanding the foregoing, the restrictions and obligations set forth in this Section 4.4(a) shall only apply to the extent that [*] or [*].

(b) Development Updates.

(i) At least once each [*], Adamas shall provide Forest with a summary of all planned Development activities for Commercialization outside of the Territory regarding any Product to be conducted by Adamas or any of its Affiliates, licensees or (sub)licensees and provide copies of all material information and data within the Adamas Know-How in the possession of Adamas as of such time and relating to the Development of any such Product that would give rise to a payment obligation to Forest under Section 6.4(d) by Adamas, its Affiliates, licensees or (sub)licensees for Commercialization outside the Territory. Without limiting the generality of the foregoing, at least once each [*] for so long as Adamas or its Affiliates, licensees or (sub)licensees continues to Develop such Product for Commercialization outside of the Territory, Adamas shall provide Forest with a reasonably detailed report describing such Development activities, in each case to the extent it has the right to provide such information; provided, however, that Adamas shall [*].

(ii) At least once each [*], Forest shall provide Adamas with a summary of all planned Development activities to be conducted by Forest or any of its Affiliates or Sublicensees regarding any FDC Product for Commercialization in the Field in the Territory and provide copies of all material information and data within the Forest Know-How in the possession of Forest and relating to the Development of any such FDC Product by Forest, its Affiliates or Sublicensees for Commercialization within the Territory. Without limiting the

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generality of the foregoing, at least once each [*] for so long as Forest or its Affiliates or Sublicensees continue to Develop such FDC Product for Commercialization in the Field in the Territory, Forest shall provide Adamas with a reasonably detailed report describing such Development activities, in each case to the extent it has the right to provide such information; provided, however, that Forest shall [*]. Adamas' use of any Program Data received from Forest shall be subject to Section 4.2(f).

(c) Coordination of Development Activities within the Territory. The Parties will work together in good faith to avoid conflicts between their respective Development activities for Products within the Territory and, if applicable, between their respective Development activities for the Products outside of the Territory, including coordinating each Party's use of clinical trial sites in the Development of the Products.

4.5 Pharmacovigilance and Recalls. Upon request by either Party to the extent required by Law, the Parties shall enter into a pharmacovigilance agreement containing reasonable and customary terms no less stringent than those required by FDA (or any applicable Regulatory Authority outside the Territory) governing the Parties' respective responsibilities relating to the exchange of safety information and data with respect to some or all Products (as required by Law). Forest shall determine whether to conduct and shall be responsible for conducting any recall or withdrawal of a Product sold by or on behalf of Forest, its Affiliates and Sublicensees in the Field in the Territory. Forest shall be responsible for all of its costs and expenses associated with any recall or withdrawal of Products pursuant to this Section 4.5; provided, however that to the extent any such recall or withdrawal resulted from Adamas' breach of its obligations hereunder or the gross negligence or willful misconduct of Adamas or any of its Affiliates, Adamas shall bear the expense of such recall or withdrawal.

ARTICLE V **COMMERCIALIZATION**

5.1 General. From and after the Effective Date, Forest shall have the sole right, at its sole cost and expense, to Commercialize the Products in the Field in the Territory in accordance with this Agreement. During the Term, Forest shall, directly or indirectly through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Commercialize a Memantine-Donepezil FDC Product in the Field in the Territory. Without limiting the foregoing, Forest agrees to conduct any promotion of an ER Product for use in combination with Donepezil in good faith and in a manner that does not intentionally discourage sales of any FDC Product for the primary purpose of benefiting from the differential royalty provisions set forth in Sections 6.4(c)(i) and 6.4(c)(iii).

5.2 Commercialization Updates. For any Calendar Year prior to the end of the ER Royalty Term, FDC Royalty Term or Proprietary Non-Donepezil FDC Royalty Term, as applicable, in which Forest or its Affiliates or Sublicensees is Commercializing a Product in the Field in the Territory, Forest shall, on [*] basis, provide Adamas with a reasonably detailed report describing such

Commercialization activities completed since the last report and planned for the next [*], no later than [*]. Following the receipt of the first approval by the FDA of an NDA for the first Memantine-Donpezil FDC Product in the Field in the Territory, the Parties

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shall meet [*] during each Calendar Year to discuss the Commercialization of the Products in the Field [*].

5.3 Conduct of Commercialization.

(a) Each Party shall not, and shall cause its Affiliates not to, and shall use Commercially Reasonable Efforts to cause each of its and its Affiliates' licensees and (sub)licensees not to, conduct any Commercialization activity regarding any Products in its respective territory that could reasonably be expected to result in a material adverse impact on the Development or Commercialization of any Products in the other Party's respective Major Market(s) (*i.e.*, in the case of Forest, with respect to a Product in the Field in the United States, and in the case of Adamas, with respect to a Product in the Field in Japan, the United Kingdom, France, Germany, Spain or Italy). Each Party shall require each of its and its Affiliates' licensees and (sub)licensees in its territory that are conducting Commercialization of any Products to be subject to the provisions of this Section 5.3(a) (or analogous provisions with substantially the same terms set forth in this Section 5.3(a)) with respect to the other Party's territory. Notwithstanding the foregoing, (i) neither Party shall be subject to any such restriction or obligation with respect to [*]; and (ii) such restrictions and obligations shall only apply to the extent that [*] or [*]. Without limiting Section 5.2, each Party shall provide the other Party, upon such other Party's reasonable request, with [*] by such first Party or any of its Affiliates, licensees or (sub)licensees, in each case to the extent such first Party has the right to provide such information; provided, however, that each Party shall [*]. Without limiting the generality of the foregoing, [*] for so long as a Party or its Affiliates, licensees or (sub)licensees continues to Commercialize any Product in which the other Party has an economic interest under this Agreement, such Party shall [*].

(b) Each Party agrees not to, and agrees to cause its Affiliates not to and agrees to use Commercially Reasonable Efforts to cause its and its Affiliates' distributors, licensees and Sublicensees (in the case of Forest) or (sub)licensees (in the case of Adamas) not to, promote or sell Products intended for its respective territory in, or otherwise encourage sales of Products into, the other Party's territory, subject to [*] and [*]. To the extent either Party becomes aware of such promotion or sales of Products into the other Party's territory, the Party who becomes aware shall promptly notify the other Party of such promotion or sale. Notwithstanding the foregoing, nothing in this clause (b) shall be construed to [*] or [*] or [*] as to which [*]. For clarity, the foregoing shall not be construed to [*].

(c) The Parties acknowledge and agree that Forest has been granted exclusive rights under the Adamas Intellectual Property to Commercialize the Products in the Field in the Territory under the licenses in Section 2.1, and Adamas has retained the exclusive rights under the Adamas Intellectual Property to Commercialize the Products in the Field outside the Territory, and the restrictions set forth in this Section 5.3 are in furtherance of the Parties' respective rights in the Territory and outside of the Territory.

5.4 Promotion of the FDC Products. The Parties acknowledge and agree, that based on their assumptions as of the Effective Date regarding (a)(i) the payer environment and formulary coverage, (ii) anticipated product label, (iii) industry marketing practices, (iv) expected approval timing, (v) expected duration of exclusivity, and (vi) commercial potential

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and market conditions, in each case with respect to the first FDC Product and (b) continued level of concomitant use by physicians of Memantine and Donepezil to treat Alzheimer's disease (collectively, the "FDC Launch Assumptions"), Forest, its Affiliates and Sublicensees, collectively shall (x) [*] during the period that begins on the First Commercial Launch of the first FDC Product and ends [*] and (y) [*] directly related to the FDC Franchise (excluding [*] set forth in clause (x)) in the Field in the Territory prior to [*] of the First Commercial Launch of the first FDC Product ((x) and (y) collectively, the "Launch Commitment") If the obligations set forth in (x) and (y) are performed, Forest shall be deemed to have satisfied its Commercially Reasonable Efforts diligence obligation

set forth in Section 5.1 with respect to Commercialization of the FDC Products prior to [*] of the First Commercial Launch of the first FDC Product. In the event of a material change in any of the FDC Launch Assumptions, as compared with the relevant conditions as of the Effective Date, such that it would no longer constitute Commercially Reasonable Efforts for Forest to undertake the Launch Commitment, Forest may make any adjustments, consistent with its Commercially Reasonable Efforts obligation in Section 5.1, to the Launch Commitment to account for such change (or changes taken as a whole) upon prior written notice to Adamas of such material change and the basis for any corresponding adjustment; provided that Forest may not adjust the Launch Commitment to provide for a level of efforts and spend that would be less than Commercially Reasonable Efforts with respect to the Commercialization of a FDC Product in the Field in the Territory. Upon Adamas' request, Forest shall review and discuss with Adamas the nature of any change in any of the FDC Launch Assumptions and any basis for any corresponding adjustment to the Launch Commitment. Any disagreement between the Parties as to whether Forest has adjusted the Launch Commitment to a level of efforts and spend that would meet Forest's obligations to use Commercially Reasonable Efforts with respect to the Commercialization of a FDC Product as set forth in this Section 5.4 shall be resolved by arbitration in accordance with Section 12.2(b). If Forest fails to meet the then-current Launch Commitment for any FDC Product, Adamas shall have the right to seek any and all available legal and equitable remedies under Section 12.2(b), including lost royalty damages in accordance with the last sentence of Section 10.5. In connection with any such proceeding under Section 12.2(b), each Party shall have the right to submit expert testimony with respect to the cause and amount of lost royalty or other damages sought.

ARTICLE VI FINANCIAL PROVISIONS

6.1 Initial License Payments. Forest shall make a non-refundable, non-creditable payment to Adamas of Sixty-Five Million Dollars (\$65,000,000) no later than five (5) Business Days after the Effective Date.

6.2 Development and Commercialization Costs. Except as otherwise expressly provided in Sections 4.1 or 4.2, each Party shall be responsible for its costs in connection with its Development of Products hereunder, and Forest shall be solely responsible for its costs in Commercializing Products in the Field in the Territory.

6.3 Event Milestone Payments.

(a) Forest shall make the milestone payments, as specified below (each, a

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“Milestone Payment”), to Adamas, based on the achievement of the corresponding milestone event specified below (each, a “Milestone Event”). Forest shall notify Adamas in writing promptly after the achievement of such Milestone Event and, subject to Section 6.3(b), pay to Adamas the corresponding Milestone Payment within [*] of the achievement of such Milestone Event.

	<u>Milestone Event</u>	<u>Milestone Payment</u>
(i)	The completion of final study report for [*] (“ <u>Bioequivalence Milestone</u> ”)	\$20,000,000
(ii)	The completion of a study report [*] to support the submission of an NDA for an FDC Product (“ <u>Stability Milestone</u> ”)	\$20,000,000
(iii)	The receipt of the first acceptance by the FDA of a submission of an NDA for an FDC Product (“ <u>Acceptance Milestone</u> ”)	1. \$25,000,000 if [*]; or 2. \$[*] if [*].
(iv)	The receipt of the first approval by the FDA of an NDA for an FDC Product (“ <u>Approval Milestone</u> ”)	1. \$30,000,000 if [*]; or 2. \$[*] if [*].

For purposes of the foregoing: only one Milestone Payment shall be paid for the achievement of each corresponding Milestone Event under this Section 6.3(a), with the maximum total Milestone Payments (if scenario 1 applies in both cases of the Acceptance Milestone and the Approval Milestone) totaling \$95,000,000 regardless of the number of acceptances or approvals for the FDC Products and no milestone payments shall be due for any other Product. For the purpose of milestones (i) and (ii) above, Forest agrees that it shall use Commercially Reasonable Efforts to [*] as soon as practicable but in any event within [*].

(b) In the event [*], then: (i) Forest shall [*] under [*] or [*] when [*] until the earlier of (1) the [*] or (2) [*], provided that if [*], [*] shall [*] (the “Outside Milestone Date”); and (ii) Forest shall [*] and [*]. In the event Forest [*] or [*] by the earlier of (1) the [*] or (2) the [*], then, if Adamas [*] and Forest [*], this Agreement shall [*] with respect to [*].

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6.4 Product Royalties and Other Payments.

(a) Royalties on FDC Products. Subject to Section 6.4(c)(ii) below, during the FDC Royalty Term, subject to Section 6.4(c) and any other applicable terms of this Agreement, Forest shall pay royalties on aggregate Net Sales in the Territory of FDC Products by Forest and its Affiliates and Sublicensees, as follows:

**Portion of Sales Year Net Sales of FDC Products in the Territory
(for the portion during the FDC Royalty Term)**

Less than or equal to \$[*]

Greater than \$[*]

Royalty Rate

[*]%

[*]%

(b) Royalties on ER Products and Other Products. During the ER Royalty Term, subject to Section 6.4(c), Forest shall pay royalties on aggregate Net Sales in the Territory of ER Products and Other Products by Forest and its Affiliates and Sublicensees, as follows:

**Portion of Sales Year Net Sales of ER Products and Other
Products in the Territory (for the portion during the ER Royalty
Term)**

Less than or equal to \$[*]

Greater than \$[*]

Royalty Rate

[*]%

[*]%

(c) Royalty Term and Adjustments.

(i) Forest’s royalty obligations to Adamas with respect to Net Sales of FDC Products in the Territory under Section 6.4(a) shall commence upon the Royalty Commencement Date (as defined in Section 6.4(c)(iv) below) for the first FDC Product in the Territory and shall continue thereafter, on a Product-by-Product basis, until the later of: (A) fifteen (15) years after First Commercial Launch of the first FDC Product in the Field in the Territory; and (B) the expiration of the last-to-expire Valid Claim of an Adamas Patent Right, including any Adamas Memantine Patent Right, that is listed in the Orange Book for such FDC Product in the Territory, except that in no event shall any royalty be due in any Calendar Quarter in which there is Generic Competition with respect to the applicable FDC Product in the Field in the Territory (the “FDC Royalty Term”). Upon expiration of Forest’s royalty obligations with respect to an FDC Product under Section 6.4(a), the licenses granted by Adamas to Forest with respect to such FDC Product under Section 2.1(a)(i) and Section 2.1(a)(ii) shall become fully-paid, perpetual and irrevocable with respect to such FDC Product.

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(ii) Notwithstanding Section 6.4(a) above, with respect to any FDC Product that contains, as its sole active ingredients, Memantine and a proprietary Cholinesterase Inhibitor owned or Controlled by Forest or its Affiliates, other than Donepezil (a “Proprietary Non-Donepezil FDC Product”), in lieu of the royalty under Section 6.4(a), Forest shall pay Adamas [*] of the Net Sales of such Proprietary Non-Donepezil FDC Products in the Territory, and such payment obligation shall commence upon the Royalty Commencement Date and shall continue, on a Product-by-Product basis, for so long as there is at least one Valid Claim of an Adamas Patent Right, including an Adamas Memantine Patent Right, in each case, that is listed in the Orange Book for such Proprietary Non-Donepezil FDC Product, as applicable, in the Territory, except that in no event shall any royalty be due in any Calendar Quarter in which there is Generic Competition with respect to the applicable Product in the Territory (the “Proprietary Non-Donepezil FDC Royalty Term”). Upon expiration of Forest’s royalty obligations with respect to a particular Proprietary Non-Donepezil FDC Product hereunder, the licenses granted by Adamas to Forest under Section 2.1(a)(i) and Section 2.1(a)(ii) shall

become fully-paid and shall remain perpetual and irrevocable with respect to such Proprietary Non-Donepezil FDC Product, respectively.

(iii) Forest's royalty obligations to Adamas with respect to Net Sales of ER Products and Other Products in the Territory under Section 6.4(b) shall commence on the Royalty Commencement Date in the Field in the Territory and shall continue, on a Product-by-Product basis, for so long as there is at least one Valid Claim of an Adamas Patent Right, including an Adamas Memantine Patent Right, in each case, that is listed in the Orange Book for such ER Product or Other Product, as applicable, in the Territory, except that in no event shall any royalty be due in any Calendar Quarter in which there is Generic Competition with respect to the applicable ER Product or Other Product, as the case may be, in the Territory (the "ER Royalty Term"). Upon expiration of Forest's royalty obligations with respect to a particular ER Product or Other Product under Section 6.4(b), the licenses granted by Adamas to Forest under Section 2.1(a)(i) and Section 2.1(a)(ii) shall become fully-paid and shall remain perpetual and irrevocable with respect to such ER Product or Other Product, respectively.

(iv) The "Royalty Commencement Date" shall mean: (A) with respect to an ER Product and Other Product, the date that is five (5) years after the First Commercial Launch of the first ER Product or Other Product, whichever is earlier, in the Field in the Territory; and (B) with respect to an FDC Product, the date that is five (5) years after the First Commercial Launch of the first FDC Product in the Field in the Territory.

(v) Orange Book Listing. The Parties shall cooperate in good faith in determining which Adamas Patent Rights will be listed in the Orange Book for each Product (other than Namenda), and the Parties agree that all Adamas Patent Rights required or permitted to be listed in the Orange Book for each Product shall be so listed. Notwithstanding the foregoing, Forest shall have the right to elect not to list a particular Adamas Patent Right in the Orange Book for a particular Product based on its good faith determination that: (A) there is a [*] for not listing such Adamas Patent Right; or (B) listing such Adamas Patent Right would be a violation of applicable Law, provided that Forest shall notify Adamas of such determination at least thirty (30) days prior to its implementation of such determination and shall consider in good faith Adamas' comments on such matter, further provided that Forest shall not make its

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determination on whether to list a particular Adamas Patent Right in the Orange Book for a particular Product primarily for the purpose of reducing Forest's financial obligation to Adamas under this Agreement.

(vi) [*] Payments by Forest. Forest shall [*] sales of an FDC Product [*] payable to Adamas pursuant to Section 6.4(a) or Section 6.4(c)(ii), as applicable, [*] Net Sales of such FDC Product after the applicable Royalty Commencement Date; provided, however, [*] the royalties on sales of such FDC Product paid to Adamas for any particular Calendar Quarter [*], provided, further, that any royalties [*] with respect to such Net Sales of such FDC Product after the Royalty Commencement Date [*] sales of such FDC Product paid to Adamas in such Calendar Quarter [*]. Forest hereby represents and warrants that, [*], there shall [*] with respect to the Net Sales of the FDC Products in the Field in the Territory [*].

(vii) Blocking Patents. If [*] cannot Manufacture or Commercialize an FDC Product in the Field in the Territory without infringing Patent Rights other than Patent Rights Controlled by Forest or its Affiliate (including those [*]) and not licensed to Forest hereunder, which Patent Rights Covers such FDC Product, unless it obtains a license to such patent from a Third Party (other than [*]) (a "Forest Blocking Patent") and pays a royalty under such license (including in connection with settlement of a patent infringement claim in accordance with Section 7.7), or (B) becomes subject to a final court or other binding order or ruling requiring the payment of a royalty to a Third Party with respect to a Forest Blocking Patent in order to Manufacture or Commercialize an FDC Product in the Field in the Territory (collectively, "Forest Third Party Patent Licenses"), [*] of any royalties paid under Forest Third Party Patent Licenses by Forest, its Affiliates or Sublicensees on Net Sales of such FDC Products after the applicable Royalty Commencement Date shall be fully creditable against royalties payable to Adamas hereunder with respect to such FDC Product; provided, however, that in no event shall such credit, together with any offset under Section 6.4(c)(vi), cause the royalties paid to Adamas with respect to such FDC Product for any particular Calendar Quarter to be reduced to less than [*] of the amount that would otherwise be payable to Adamas for such Calendar Quarter pursuant to Section 6.4(a) or Section 6.4(c)(ii), as applicable, provided, further, that any such royalty paid on sales of such FDC Product after the Royalty Commencement Date under Forest Third Party Patent Licenses by Forest that is not used by Forest in a particular Calendar Quarter to reduce royalties on sales of such FDC Product paid to Adamas in such Calendar Quarter may be carried over to subsequent Calendar Quarters until fully used in accordance with this Section 6.4(c)(vii).

(viii) Authorized Generics. In the event Forest, either by itself or through its Affiliates or Sublicensees, Commercializes one (1) or more products that are Authorized Generics with respect to a Product, then Forest shall pay to Adamas royalties on the Net Sales of such Authorized Generics in an amount [*].

(d) Consideration to Forest for Rights to Use Certain Forest Know-How Outside the Territory.

(i) Payments. (A) In the event that (x) Adamas or its Affiliates grants, sells or transfers to any Third Party rights, or otherwise enables such Third Party, to Develop or Commercialize any Product in the Field outside the Territory other than Japan (a "Transaction")

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and (y) Adamas or its Affiliates or such Third Party (or any (sub)licensees or distributors of, or other Persons acting on behalf of, any of the foregoing), in connection with or pursuant to such Transaction, (1) incorporates or references (including by way of a right of reference) or relies upon any Program Data in any regulatory filing for any Product in support of Regulatory Approval (other than in Japan) of such Product, unless at the time of such incorporation or reference or reliance, any Third Party would have the right to incorporate or reference such Program Data, in an analogous regulatory filing in support of an analogous Regulatory Approval in the same jurisdiction, without a license from Forest, its Affiliates or licensees and such Third Party would not require a license or consent from Adamas, its Affiliates or licensees in order to file for such Regulatory Approval or sell the Product in such jurisdiction, or (2) incorporates or references any Program Data in marketing materials for any Product for use in any country other than Japan, unless at the time of such incorporation or reference in the applicable jurisdiction, any Third Party would be able to do so without a license from Forest, its Affiliates or licensees, but excluding in each case ((1) and (2)) any use of Program Data permitted by Section 4.2(f) (any of the foregoing incorporation, reference or reliance, a "Triggering Act"), then Adamas shall pay to Forest [*] of Sublicensing Revenues received by Adamas or its Affiliates from such Third Party for the Transaction that is reasonably allocated to such Product (which payment shall be made within [*] after the receipt of the corresponding Sublicensing Revenue from the Third Party); and (B) in the event that Adamas or its Affiliates engages in a Triggering Act, Adamas shall pay to Forest a royalty equal to [*] of aggregate net sales of such Product in such countries of sale other than Japan (where such net sales shall be calculated based on the definition of Net Sales, but on sales of Adamas and its Affiliates to a Third Party, rather than sales of Forest and its Affiliates and Sublicensees, *mutatis mutandis*) (which payment shall be made within [*] after the end of each Calendar Quarter for such net sales in such Calendar Quarter). For clarity, Adamas' Sublicensing Revenue sharing obligation under clause (A) above shall not apply to any amounts received by Adamas or its Affiliates in consideration of rights granted to a Third Party with respect to Japan, and Adamas' royalty obligation under clause (B) above shall not apply to net sales of Products in Japan. In the event that any payments required to be made by Adamas to Forest pursuant to this Section 6.4(d)(i) are subject to additional withholding tax, Adamas shall take all actions necessary to obtain any tax benefit (including through the use of foreign tax credit) with respect to any amounts withheld or deducted for purposes of calculating Sublicensing Revenue and to defend such benefit in a tax audit (and the amount of any such benefit shall be included in Sublicensing Revenue).

(ii) Payment Term. Adamas' obligation to pay the royalty set forth in clause (B) above shall commence on the First Commercial Launch by Adamas or its Affiliates or (sub)licensees of the first Product that would give rise to a payment obligation to Forest under Section 6.4(d) in the Field outside of the Territory and shall continue thereafter on a Product-by-Product basis and country-by-country basis until fifteen (15) years after First Commercial Launch of such first Product in the Field outside of the Territory, except that in no event shall any royalty be due in any Calendar Quarter in which there is Generic Competition with respect to the applicable Product in the applicable country.

(iii) [*] Payments and other Third Party Payments by Adamas. Adamas shall have the right to deduct from any amounts otherwise payable to Forest pursuant to this Section 6.4(d) on a Product-by-Product basis an amount equal to [*] of any amounts paid

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by Adamas to [*] or its licensees as consideration for a grant of rights from [*] (or such licensee) with respect to the applicable Product (outside the Territory, other than Japan) (collectively “[*] Payments”); provided, however, that in no event shall such offset, together with any offset under Section 6.4(d)(iv), cause the amounts due to Forest pursuant to this Section 6.4(d) for any particular Calendar Quarter for any country to be reduced (A) in any case of Section 6.4(d)(i)(A), to less than [*] of the amount that would otherwise be payable to Forest for such Calendar Quarter for such country pursuant to such clause, or (B) in any case of Section 6.4(d)(i)(B), to less than [*] of the amount that would otherwise be payable to Forest for such Calendar Quarter pursuant to such clause; and provided, further, that any [*] Payments that are not able to be used by Adamas in a particular Calendar Quarter as deductions under this Section 6.4(d) due to the foregoing limits on deductions may be carried over to subsequent Calendar Quarters until fully used in accordance with this Section 6.4(d)(iii)(A) or (B), as applicable. This Section 6.4(d) shall survive any termination or expiration of this Agreement. In addition, to the extent that any amounts paid by Adamas to [*] are required to be paid through to Forest or its Affiliate under the [*] Agreements or other arrangement between Forest or its Affiliates and [*], Adamas may deduct [*] of such amounts from any payments to Forest under this Section 6.4(d), without limit and such deductions shall not be taken into account when calculating the Sublicensing Revenue and royalty floor amounts under Section 6.4(d)(iii)(A) and (B) above.

(iv) Blocking Patents. If Adamas (A) reasonably determines that it cannot Manufacture or Commercialize a Product for which compensation is due to Forest under Section 6.4(d) in the Field outside the Territory without infringing Patent Rights other than Patent Rights Controlled by Adamas or its Affiliate (or those licensed to Forest by [*] under the [*] Agreements) and not licensed to Adamas hereunder, which Patent Rights Cover such Product unless it obtains a license to such patent from a Third Party (other than from [*] or any of its licensees) (an “Adamas Blocking Patent”) and pays a royalty under such license (including in connection with settlement of a patent infringement claim in accordance with Section 7.7), or (B) becomes subject to a final court or other binding order or ruling requiring the payment of a royalty to a Third Party with respect to an Adamas Blocking Patent in order to Manufacture or Commercialize such Product in the Field outside the Territory (collectively, “Adamas Third Party Patent Licenses”), [*] of any royalties paid under Adamas Third Party Patent Licenses by Adamas, its Affiliates or (sub)licensees on net sales of such Product for which Adamas has a payment obligation to Forest under Section 6.4(d)(i)(B) shall be fully creditable against royalties and Sublicensing Revenue payments payable to Forest under Sections 6.4(d)(i)(A) and (B) with respect to such Product; provided, however, that in no event shall such offset, together with any offset under Section 6.4(d)(iii), cause the amounts due to Forest pursuant to Section 6.4(d)(i) for any particular Calendar Quarter for any country to be reduced (A) in any case of Section 6.4(d)(i)(A), to less than [*] of the amount that would otherwise be payable to Forest for such Calendar Quarter for such country pursuant to such clause or (B) in any case of Section 6.4(d)(i)(B), to less than [*] of the amount that would otherwise be payable to Forest for such Calendar Quarter pursuant to such clause; provided, further, that any such royalty paid under Adamas Third Party Patent Licenses by Adamas that is not used by Adamas in a particular Calendar Quarter to reduce royalties paid to Forest in such Calendar Quarter may be carried over to subsequent Calendar Quarters until fully used in accordance with this Section 6.4(d)(iv).

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(e) Acknowledgement of Blended Royalty.

(i) The Parties hereby acknowledge and agree that royalties may become payable by Forest to Adamas hereunder for Products for which there are no Valid Claims of an Adamas Patent Right, including any Adamas Memantine Patent Right, and that such royalties are in consideration of each of the following, separately and together: (A) Adamas’ expertise and Know-How relating to the Products and (B) licenses granted to Forest with respect to the Adamas Know-How that is not within the claims of any Adamas Patent Right, including any Adamas Memantine Patent Right. The Parties agree that the royalty rates set forth in Section 6.4(a), (b) and (c) reflect an efficient and reasonable blended allocation of the value provided by Adamas to Forest.

(ii) The Parties hereby acknowledge and agree that royalties payable by Adamas to Forest hereunder for Products are in consideration of the benefit to Adamas, its Affiliates and (sub)licensees from their use of the Program Data if and when applicable in connection with the applicable Product. The Parties agree that the royalty rates set forth in Section 6.4(d) reflect an appropriate allocation of the value provided by Forest to Adamas.

6.5 Reports; Payments.

(a) Within [*] after the end of each Calendar Quarter during which there are Net Sales giving rise to a payment obligation under Section 6.4(a), 6.4(b), 6.4(c)(ii) or 6.4(c)(viii), Forest shall submit to Adamas a report identifying, for each Product for which a royalty is due thereupon, the Net Sales for such Product in the Territory for such Calendar Quarter, the applicable royalty rate, any royalty payable to Adamas and the basis for any reduction in royalties pursuant to any subsection of Section 6.4; provided that the first such report (and the associated payment) with respect to a Product Category shall not be due until after the end of the first full

Calendar Quarter after the First Commercial Launch of the first Product in such Product Category and shall cover the period from such First Commercial Launch until the end of such first full Calendar Quarter. Concurrently with each such report, Forest shall pay to Adamas all royalties payable by it under Section 6.4. Notwithstanding the foregoing, Forest shall have the right to deduct from any amounts otherwise owed to Adamas under Section 6.4(a), 6.4(b), 6.4(c)(ii), or 6.4(c)(viii) any damages that Forest has been awarded under Section 12.2(b)(ii) or (b)(iii) as a result of Adamas' breach of this Agreement that have not then been paid by Adamas or previously deducted under this sentence. Prior to the time that a royalty report is due under this Section 6.5(a) above for a particular Product, Forest shall provide Adamas with reports for each half Calendar Year setting forth its Net Sales of such Product during such half Calendar Year, within [*] after the end of such half Calendar Year.

(b) Within [*] after the end of each Calendar Quarter during which there are net sales of Products (which shall be determined in the same manner as Net Sales as described in Section 6.4(d)) for which Adamas has a payment obligation to Forest under Section 6.4(d)(i)(B) or during which Adamas receives Sublicensing Revenue for which Adamas has a payment obligation to Forest under Section 6.4(d)(i)(A), Adamas shall submit to Forest a report identifying such net sales of such Products outside of the Territory for which Adamas has a payment obligation to Forest under Section 6.4(d)(i)(B) for such Calendar Quarter, the applicable royalty rate, any royalty payable to Forest and the basis for any reduction in royalties pursuant to

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any subsection of Section 6.4, or the amount of Sublicensing Revenue received by Adamas as described in Section 6.4(d)(i)(A) for such Calendar Quarter. Concurrently with each such report, Adamas shall pay to Forest royalties payable by it in accordance with Section 6.4(d).

6.6 Books and Records; Audit Rights.

(a) Forest shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and Payments, including those required by Sections 6.4(a), (b), and (c). Adamas shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by Adamas and reasonably acceptable to Forest, review any such records of Forest in the location(s) where such records are maintained by Forest upon reasonable notice (which shall be no less than [*] prior notice) and during regular business hours and under reasonable obligations of confidence, for the sole purpose of verifying the basis and accuracy of Payments made or due under Sections 6.4(a), (b), and (c) or otherwise under this Agreement within the [*] period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or Payment submitted by Forest during such period is accurate or inaccurate and the actual amounts of Net Sales, and royalties or other Payment due, for such period. Should such inspection lead to the discovery of a discrepancy to Adamas' detriment, Forest shall pay within [*] after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.9. Adamas shall pay the full cost of the review unless the underpayment of royalties is greater than [*] of the amount due for the applicable period, in which case Forest shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Forest revealed by an examination shall be fully creditable against future Payments.

(b) Adamas shall keep complete and accurate records relating to the calculations of net sales of Products for which Adamas has a payment obligation to Forest under Section 6.4(d)(i)(B) (as calculated pursuant to Section 6.4(d)) and the Sublicensing Revenue payments required to be made to Forest under Section 6.4(d)(i)(A). Forest shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by Forest and reasonably acceptable to Adamas, review any such records of Adamas in the location(s) where such records are maintained by Adamas upon reasonable notice (which shall be no less than [*] prior notice) and during regular business hours and under reasonable obligations of confidence, for the sole purpose of verifying the basis and accuracy of payments made under Section 6.4(d) within the [*] period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or payment submitted by Adamas during such period is accurate or inaccurate and the actual amounts of net sales of such Products outside of the Territory for which Adamas has a payment obligation to Forest under Section 6.4(d)(i)(B) (calculated in accordance with Section 6.4(d)), royalties due, and Sublicensing Revenue payments due to Forest under Section 6.4(d)(i)(A) for such period. Should such inspection lead to the discovery of a discrepancy to Forest's detriment, Adamas shall pay within [*] after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculate in accordance with Section 6.9. Forest shall pay the full cost of the review unless the underpayment of royalties or other amounts due is greater than [*] of the amount due for the applicable period, in which case Adamas shall

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pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Adamas revealed by an examination shall be fully creditable against future payments to Forest under Section 6.4(d).

6.7 Tax Matters. No payments required to be made hereunder shall be reduced on account of any taxes unless required by Law. Adamas alone shall be responsible for paying any and all taxes (other than withholding taxes required by Law to be deducted and paid on Adamas' behalf by Forest) levied on account of, or measured in whole or in part by reference to, any Payments Adamas receives. Forest alone shall be responsible for paying any and all taxes (other than withholding taxes required by Law to be deducted and paid on Forest's behalf by Adamas) levied on account of, or measured in whole or in part by reference to, any payments that Forest receives. The Parties shall cooperate in good faith to obtain the benefit of any relevant tax treaties to minimize as far as reasonably possible any taxes that may be levied on any Payments or payments received by Forest. Each Party shall deduct or withhold from the payments made to the other Party any taxes that it is required by Law to deduct or withhold. Notwithstanding the foregoing, if either Party is entitled under any applicable tax treaty to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to the other Party or the appropriate Governmental Authority (with the assistance of the other Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the other Party of its obligation to withhold tax, and the other Party shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be, provided that such other Party has received evidence of the first Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [*] prior to the time that the payment to the first Party is due. If, in accordance with the foregoing, the paying Party withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount, and send to the other Party proof of such payment within [*] following that latter payment. Forest represents and warrants that, to its knowledge, no withholding tax will be due on the payments made by Forest pursuant to Section 6.1, 6.3 or 6.4 based on the jurisdictions of the Parties and Law, in each case, in effect as of the Effective Date. In the event that either Party assigns this Agreement to an Affiliate or Third Party and, as a result of such assignment, payments made hereunder are subject to additional withholding tax, such assigning Party shall be responsible for the resulting additional withholding taxes; provided, that if the non-assigning Party derives a tax benefit (including through the use of foreign tax credit) determined on a with and without basis as a result of such additional withholding, then the non-assigning Party shall promptly reimburse the assigning Party for the amount of such benefit; provided further that the non-assigning Party shall take all actions necessary to obtain any tax benefit (including through the use of foreign tax credit) with respect to such additional withholding taxes and to defend such benefit in a tax audit.

6.8 Payment Method and Currency Conversion. All payments made pursuant to this Agreement shall be made in US dollars in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, in the case of payments to Adamas, to Adamas' bank account at [*], or to such other bank account as Adamas shall designate in a notice at least ten (10) days before the payment is due, or, in the case of payments to Forest, to Forest's bank account at [*] or to such other bank account as Forest shall designate in a notice at least ten (10) days before the payment is due.

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Each Party's wiring instructions are set forth on Schedule 6.8. For the purposes of determining the amount of any consideration payable [*], the amount of any such consideration in any foreign currency shall be converted into another currency in accordance with the prevailing rates of exchange for the relevant month for converting such first currency into such other currency used by such paying Party's internal accounting systems, which are independently audited on an annual basis. Upon request by the non-paying Party, the paying Party shall disclose the bases for the rates of exchange used for purposes of assuring that such rates reflect prevailing rates of exchange.

6.9 Late Payments. If a Party shall fail to make a timely payment pursuant to the terms of this Agreement, the other Party shall provide written notice of such failure to the non-paying Party (a "Late Payment Notice"), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice as follows:

(a) for amounts [*] or fewer days past due, the rate applied shall be the [*] US dollar LIBOR rate effective for the date that payment was due (as published in the Wall Street Journal), computed for the actual number of days after the date of the Late Payment Notice that the payment was past due; and

(b) for amounts greater than [*] past due, the rate applied shall be the [*] US dollar LIBOR rate effective for the date that payment was due (as published in the Wall Street Journal) plus [*] per annum, computed for the actual number of days after the date of the Late Payment Notice that the payment was past due; provided, however, in the event of any dispute with respect to any amount payable by a Party under this Agreement, such Party, at its option, may (i) pay such disputed amount to the other Party and if the dispute is resolved in favor of the paying Party, then within [*] after the resolution of such dispute, the non-paying Party shall reimburse the paying Party for the amount of such payment plus interest at the [*] US dollar LIBOR rate effective for the date that the paying Party made such payment (as published in the Wall Street Journal) plus [*] per annum, computed for the actual number of days after the date the paying Party made such payment until the date the non-paying Party reimburses the paying Party or (ii) elect to withhold payment during the pendency of the dispute, in which case if the dispute is resolved against such Party this Section 6.9(b) shall apply.

6.10 Other Amounts Due. Unless otherwise specified in this Agreement, all amounts required to be paid by a Party under this Agreement shall be paid by such Party within [*] after receipt of an invoice therefor.

ARTICLE VII INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 Joint IP Working Group. Promptly following the Effective Date, the Parties shall establish a joint working group consisting of at least one (1) designee of Adamas and at least one (1) designee of Forest, each of which shall have experience in the prosecution, enforcement and defense of intellectual property rights in the pharmaceutical field (the “Joint IP Working Group” or “JIPWG”). Each Party may change its designee(s) on the JIPWG upon written notice to the other Party. The JIPWG shall be responsible for coordinating all material activities and material

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communications relating to the prosecution, maintenance and enforcement of the Adamas Memantine Patent Rights in the Territory and for coordinating all other material communications between the Parties with respect to the Adamas Patent Rights that are not Adamas Memantine Patent Rights and the Forest Patent Rights. The JIPWG shall strive to reach consensus with respect to such matters; provided, however, that, in the event that consensus cannot be reached, (a) subject to any applicable provisions of Section 7.3, [*] the applicable Adamas Patent Right, including any Adamas Memantine Patent Right, or Forest Patent Right, as the case may be, shall [*] with respect to such prosecution and maintenance and (b) [*] any Adamas IP Infringement Claim or Invalidity Claim shall [*] with respect to such action; in each case as more fully described in, and subject to, this ARTICLE VII.

7.2 Ownership of Know-How and Patents. Subject to the rights and obligations of the Parties hereunder: (a) [*] shall own all Know-How (and all Patent Rights in such Know-How) that is developed, created, conceived or first reduced to practice by employees or agents or subcontractors of [*] or its Affiliates in carrying out any Development activity pursuant to ARTICLE IV of this Agreement during the Term, with or without employees or agents or subcontractors of [*] or its Affiliates, that [*] (such Know-How, the “Joint Know-How” and such Patent Rights, the “Joint Patent Rights”), on a worldwide basis, and (b) [*] shall own all [*], on a worldwide basis. For clarity, without limitation of any rights of [*] hereunder, [*] shall have the right to practice the Joint Know-How and the Joint Patent Rights for any purpose, and to license others to do the same, without obtaining the consent of or accounting to [*]. For clarity, Joint Know-How shall exclude any [*]. The determination of whether any invention is conceived or reduced to practice by or on behalf of a Party or an Affiliate thereof for the purpose of determining whether it constitutes Joint Know-How shall, for purposes of this Agreement, be made in accordance with the laws of inventorship under the US patent laws as such laws exist as of the Effective Date. Each Party hereby assigns to the other Party such of its right, title and interest in any Know-How developed, created, conceived or first reduced to practice under this Agreement as necessary to effect the ownership rights set forth above. [*] shall execute and deliver to [*], without additional compensation, all documents that are necessary to assign and otherwise transfer the [*] to [*] as is necessary to fully effect the ownership thereof by [*]. [*] shall execute and deliver to [*], without additional compensation, all documents that are necessary to assign and otherwise transfer the [*] to [*] as is necessary to fully effect the ownership thereof by [*]. Notwithstanding anything to the contrary [*], [*] shall not [*] any [*], except that [*]

may [*] included in [*] to the extent legally required or necessary [*] for Products, but in no event shall [*] for the purpose of [*], including any [*] and any [*].

7.3 Prosecution and Maintenance of Patent Rights.

(a) Prosecution of Adamas Memantine Patent Rights.

(i) Prosecution and Maintenance. [*] prepare, file, prosecute and maintain (including with respect to related interference, derivation, re-issuance, re-examination, opposition and other post-grant proceedings) the Adamas Memantine Patent Rights in the Territory. Adamas and Forest shall cooperate through the JIPWG in connection with the continued prosecution and maintenance [*] of the Adamas Memantine Patent Rights, and the JIPWG shall discuss and shall strive to agree upon a strategy for the prosecution and maintenance [*] of the Adamas Memantine Patent Rights. Subject to this Section 7.3(a)(i), if

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consensus cannot be reached by the JIPWG with respect to any matter relating to the prosecution and maintenance of the Adamas Memantine Patent Rights in the Territory, including whether to file a patent application in the Territory, [*] shall have the final decision-making authority regarding such prosecution and maintenance; provided that [*] shall consider in good faith [*] reasonable proposals or comments as part of such filing, prosecution and maintenance. At all times during the Term, [*] shall have the right to review and comment on the documentation, filings and communications to or from the US Patent and Trademark Office (or any successor agency) (including reasonable access thereto) related to the Adamas Memantine Patent Rights, and [*] shall keep [*] reasonably informed of the status of all pending patent applications that pertain to the Adamas Memantine Patent Rights. [*]: (1) [*] shall incorporate [*] reasonable proposals or comments as part of such filing, prosecution or maintenance, and (2) [*] shall use for the filing and prosecution of the Adamas Memantine Patent Rights patent counsel [*], which [*] patent counsel for the Adamas Memantine Patent Rights [*]; provided, however, in the event that [*] reasonably believes that [*] is [*] the Adamas Memantine Patent Rights, [*] shall have the right to elect to change patent counsel to patent counsel [*], such [*]. On and after the Effective Date, such [*] patent counsel shall [*], and [*] with respect to such filing and prosecution. If, [*], [*] decides to abandon any Adamas Memantine Patent Rights, [*] shall, at its sole expense, have the option to continue to prosecute and maintain such Patent Rights, in which case such Patent Rights shall [*], but, for clarity, shall [*]. If, [*], [*] decides to abandon any Adamas Memantine Patent Rights, [*] shall, at its sole expense, have the option to continue to prosecute and maintain such Patent Rights [*], provided that (1) any such prosecution and maintenance by [*] shall [*] with respect to the other Adamas Memantine Patent Rights; (2) [*] shall (A) keep [*] reasonably informed of the status of all pending patent applications that pertain to such Adamas Memantine Patent Rights, (B) incorporate [*] reasonable proposals or comments as part of such filing, prosecution or maintenance, and (C) use for the filing and prosecution of such Adamas Memantine Patent Rights patent counsel [*]; and (3) for clarity, such Adamas Memantine Patent Rights shall [*]. If (A) the prosecuting Party's intended position in the prosecution or maintenance of an Adamas Memantine Patent Right would be reasonably expected to have a material adverse effect on the non-prosecuting Party's interest in and rights to the [*] (including the licenses granted hereunder), the [*] (in case of [*] an Adamas Memantine Patent Right), or the Commercialization of the Products in the Field in the non-prosecuting Party's territory and (B) the non-prosecuting Party notifies the prosecuting Party of its objection to such prosecution or maintenance position, the Parties shall meet and discuss the non-prosecuting Party's objection in good faith and use reasonable efforts to determine a mutually agreeable prosecution or maintenance strategy, provided that if the Parties fail to agree and the non-prosecuting Party maintains its objection, [*].

(ii) General Provisions. With respect to [*] prosecution and maintenance of the Adamas Memantine Patent Rights under Section 7.3(a)(i), [*] and its Affiliates will not take (and shall not grant to any Third Party the right to take) any action (including by reissue or reexamination) to [*] any Adamas Memantine Patent Rights to [*]. In the event [*] any Adamas Memantine Patent Rights to any of its Affiliates or a Third Party, [*] shall (A) condition [*] upon an express written agreement of such Affiliate or Third Party to be bound by the restrictions of Section 7.3(a) to the same extent as [*], (B) be responsible for such Affiliate's or Third Party's compliance with such restrictions, (C) promptly provide to [*]

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written evidence of compliance with the obligation set forth in Section 7.3(a)(ii)(A), and (D) cooperate with [*] regarding the enforcement of such restrictions.

(b) No Challenge. Except to the extent required under applicable Law, if: (i) Forest or any of its Affiliates or Sublicensees (including [*] under this Agreement), or (ii) [*], [*] or any [*] (if [*] under this Agreement), intentionally commences, participates in, solicits, actively supports or encourages any challenge to the validity or enforceability of any Patent Rights in the Territory within the Adamas Patent Rights (including the Adamas Memantine Patent Rights) before any Governmental Authority, or causes or requests a review of the same by any such Governmental Authority (a “Forest Patent Challenge”) and does not effectively withdraw and eliminate such Forest Patent Challenge within [*] after written notice by Adamas to Forest, then, effective upon the end of such [*] period: (A) [*] set forth in [*] shall [*] with respect to [*] and [*] with respect to [*]; (B) any [*] shall [*]; and (C) [*] shall [*] of the [*] and any [*]. For clarity, if [*] an Adamas Patent Rights that [*] as a result of a Forest Patent Challenge, then [*], such [*] will [*] for purposes of [*] hereunder. During the Term, Adamas shall provide Forest from time to time with a list of Patent Rights constituting the Adamas Patent Rights (including the Adamas Memantine Patent Rights) in the Territory to enable Forest to comply with the terms of this Section 7.3(b). Notwithstanding anything to the contrary in this Agreement, Forest shall have the right to [*] for the sole purpose of [*] compliance with the terms of this Section 7.3(b). Further, unless and until an Adamas Patent Right is included on such list, the provisions of this Section 7.3(b) shall not apply to such Adamas Patent Right.

(c) Prosecution of Adamas Patent Rights; Related Adamas Patent Rights.

(i) Adamas shall have the sole right, but not the obligation, at its cost and expense, to prepare, file, prosecute and maintain (including with respect to related interference, derivation, re-issuance, re-examination, opposition and other post-grant proceedings) the Adamas Patent Rights (other than the Adamas Memantine Patent Rights) anywhere in the world. Adamas shall keep Forest informed as to prosecution matters with respect to Adamas Patent Rights, to the extent such Adamas Patent Rights [*], through the JIPWG, and Adamas shall consider in good faith any comments provided by Forest with respect to such prosecution matters. In the event any such Adamas Patent Right [*], Adamas shall [*]. [*] shall [*]. If Adamas’ intended position in the prosecution or maintenance of the Adamas Patent Rights pursuant to this Section 7.3(c)(i) would be reasonably expected to have a material adverse effect on the Commercialization of the Products in the Field in the Territory and Forest notifies Adamas of its objection to such prosecution or maintenance position, the Parties shall meet and discuss such objection in good faith and use reasonable efforts to determine a mutually agreeable prosecution or maintenance strategy, provided that if the Parties fail to agree and Forest maintains its objection, [*].

(ii) If Adamas’ intended position in the prosecution or maintenance of the Related Adamas Patent Rights would be reasonably expected to have a material adverse effect on the Commercialization of the Products in the Field in the Territory and Forest notifies Adamas of its objection to such prosecution or maintenance position, the Parties shall meet and discuss such objection in good faith and use reasonable efforts to determine a mutually agreeable

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prosecution or maintenance strategy, provided that if the Parties fail to agree and Forest maintains its objection, [*].

(d) Prosecution of Forest Patent Rights.

(i) Forest shall have the sole right, but not the obligation, at its cost and expense, to prepare, file, prosecute and maintain (including with respect to related interference, derivation, re-issuance, re-examination, opposition and other post-grant proceedings) the Forest Patent Rights (other than the [*] as to which [*], [*] as described in [*]) anywhere in the world. Forest will keep Adamas reasonably informed with respect to the prosecution and maintenance of the Forest Patent Rights through the JIPWG, and Forest shall consider in good faith any comments provided by Adamas with respect to such prosecution matters. If Forest’s intended position in the prosecution or maintenance of the Forest Patent Rights pursuant to this Section 7.3(d) (i) would be reasonably expected to have a material adverse effect on effect on the Commercialization of the Products in the Field outside the Territory and Adamas notifies Forest of its objection to such prosecution or maintenance position, the Parties shall meet and discuss such objection in good faith and use reasonable efforts to determine a mutually agreeable prosecution or maintenance strategy, provided that if the Parties fail to agree and Adamas maintains its objection, [*].

(ii) No Challenge. Except to the extent required under Law, in the event that Adamas or any of its Affiliates or (sub)licensees intentionally commences, solicits or encourages any challenge to the validity or enforceability of any Patent Rights in the Territory owned or Controlled by Forest that Cover a Product before any Governmental Authority, or causes or requests a review of the same by any such Governmental Authority (an “Adamas Patent Challenge”) and does not effectively withdraw and eliminate such Adamas Patent Challenge within [*] after written notice by Forest to Adamas, then, effective upon the end of such [*] period, (A) [*] set forth in [*] shall [*], (B) any [*] shall [*], and (C) [*] shall [*] of the [*] and any [*]. During the Term, Forest shall provide Adamas from time to time with a list of Patent Rights Controlled by Forest and subject to this Section 7.3(d)(ii) to enable Adamas to comply with the terms of this Section 7.3(d)(ii). Notwithstanding anything to the contrary in this Agreement, Adamas shall have the right to [*] for the sole purpose of [*] compliance with the terms of this Section 7.3(d)(ii). Further, unless and until a Patent Right is included on such list, the provisions of this Section 7.3(d)(ii) shall not apply to such Patent Right. In the event Forest or any of its Affiliates or (sub)licensees initiates any claim, suit or proceeding that asserts or enforces any Patent Rights owned or Controlled by Forest in the Territory against Adamas or any of its Affiliates or (sub)licensees with respect to any product other than a Product, then Adamas (or its Affiliate or (sub)licensee, as applicable) shall have the right to defend such claim, suit or proceeding with respect to such product (subject to the other provisions of this Agreement), notwithstanding this Section 7.3(d)(ii), and the foregoing [*] shall not apply by reason of such defense.

(iii) Forest shall not, and shall ensure that its Affiliates shall not, and shall not enable any licensees, collaborators or Sublicensees to, without the prior written consent of Adamas, file, prosecute or maintain any Patent Right with respect to the Forest Know-How outside the Territory that [*], or [*] or [*], or [*] in accordance with [*] or [*] or [*] under this Agreement, either [*] or [*].

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(e) Prosecution of Joint Patent Rights. If [*] decides not to file or to abandon any Joint Patent Right, [*] shall, at its sole expense, have the option to file or continue to prosecute and maintain such Joint Patent Right [*], and [*] shall consider in good faith any comments provided by [*] with respect to such prosecution matters; provided, however, that if [*] any such Joint Patent Right [*] for [*], [*] prosecute any such Joint Patent Rights pursuant to this Section 7.3(e). Any Joint Patent Right prosecuted and maintained by [*] pursuant to this Section 7.3(e) shall [*] and shall [*] and [*], as applicable. If [*] intended position in the prosecution or maintenance of the Joint Patent Rights pursuant to this Section 7.3(e) would be reasonably expected to have a material adverse effect on the Commercialization of the Products in the Field [*] and [*] notifies [*] of its objection to such prosecution or maintenance position, the Parties shall meet and discuss such objection in good faith and use reasonable efforts to determine a mutually agreeable prosecution or maintenance strategy, provided that if the Parties fail to agree and [*] maintains its objection, [*].

(f) Cooperation. The Parties shall coordinate so that, to the extent practicable, there are separate patent applications for the Forest Patent Rights [*], on the one hand, and the Adamas Patent Rights, including Adamas Memantine Patent Rights, on the other.

(g) Notices and Encumbrances. Each Party shall execute and file those notices and other filings as the other Party shall reasonably request be made from time to time with the US Patent and Trademark Office (or any successor agency or any corresponding Governmental Authority outside the Territory) with respect to the rights granted to the other Party under this Agreement, with associated reasonable, documented, out-of-pocket costs and expenses to be reimbursed promptly by the requesting Party.

(h) CREATE Act. The Parties acknowledge and agree that this Agreement is a “joint research agreement” as defined in the CREATE Act (or, after March 16, 2013, 35 U.S.C. § 100(h)). Notwithstanding anything to the contrary in this ARTICLE VII, each Party may at any time make an election under the CREATE Act when exercising its rights under this ARTICLE VII without the prior written consent of the other Party. In the event a Party makes an election under the CREATE Act in accordance with this Section 7.3(h), the other Party shall cooperate and coordinate its activities with the electing Party with respect to any submissions, filings or other activities in support thereof. Without limiting the foregoing, each Party may use the contents of Schedule 7.3(h) in exercising its rights hereunder with respect to any such election under the CREATE Act.

7.4 Third Party Infringement of Adamas Patent Rights.

(a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Adamas Patent Rights by a Product in the Field in the Territory, or (ii) unauthorized use or

misappropriation of any of the Adamas Know-How with respect to a Product in the Field in the Territory (each case, except with respect to any Adamas Paragraph IV Claim subject to Section 7.11, an “Adamas IP Infringement Claim”), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Adamas IP Infringement Claim. Adamas shall also promptly report in writing to Forest during the Term any infringement of any Forest Patent Right

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by an FDC Product or any unauthorized use or misappropriation with respect to an FDC Product of any Forest Know-How anywhere in the world, in each case of which Adamas becomes aware.

(b) Initial Right to Enforce. Subject to Sections 7.4(c) through 7.4(f), Forest shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the Adamas Intellectual Property relating to a Product in the Field in the Territory, with respect to an Adamas IP Infringement Claim; provided that the provisions of Section 7.6 shall govern the right to defend any challenge to the validity or enforceability of any Adamas Patent Right brought in connection with such action. Any such suit by Forest shall be brought either in the name of Adamas or its Affiliate, the name of Forest or its Affiliate, or jointly by Forest, Adamas and their respective Affiliates, as may be required by the Law of the forum and Adamas shall join any action brought by Forest pursuant to this Section 7.4(b) if requested by Forest, at Forest’s expense, and otherwise shall have the right to participate, at its sole expense, in such action. Adamas shall execute such legal papers and cooperate in the prosecution of any such suit as may be reasonably requested by Forest; provided that Forest shall promptly reimburse Adamas’ reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by Adamas in connection with such cooperation. In respect of any enforcement action brought by Forest pursuant to this Section 7.4(b), except to the extent prohibited by Laws or a court order, Forest shall (i) keep Adamas reasonably informed regarding Forest’s actions with respect to the enforcement of the Adamas Intellectual Property and (ii) promptly provide Adamas with copies of all documents and other materials filed by any party to such enforcement action with the court before which such enforcement action is pending. [*], Forest shall [*] Adamas’ reasonable proposals or comments with respect to such enforcement. [*], Forest shall [*] Adamas’ reasonable proposals or comments with respect to such enforcement.

(c) Step-In Right. [*], if Forest does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Adamas IP Infringement Claim pursuant to Section 7.4(b) within [*] of a Party providing notice of such Adamas IP Infringement Claim under Section 7.4(a), then Adamas may, in its discretion, provide Forest with notice of Adamas’ intent to initiate a suit or take other appropriate action. If Adamas provides such notice and Forest does not initiate a suit within [*] after receipt of such notice from Adamas, then Adamas shall, subject to Section 7.4(d), have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect or enforce the Adamas Intellectual Property; provided that the provisions of Section 7.6 shall govern the right to defend any challenge to the validity or enforceability of any Adamas Patent Right brought in connection with such action. Notwithstanding the foregoing, if [*] a suit or taking other action to protect or enforce the Adamas Intellectual Property pursuant to this Section 7.4(c) that [*], [*] enforce such Adamas Intellectual Property pursuant to this Section 7.4(c); provided, however, that [*] an enforcement action with respect to the Adamas Intellectual Property based on considerations of [*] under this Agreement. Any suit by Adamas shall be either in the name of Adamas or its Affiliate, the name of Forest or its Affiliate, or jointly by Forest, Adamas and their respective Affiliates, as may be required by the Law of the forum. Forest shall join any action brought by Adamas pursuant to this Section 7.4(c) if requested by Adamas, at Adamas’ expense,

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and otherwise shall have the right to participate, at its sole expense, in such action. Forest shall execute such legal papers and cooperate in the prosecution of any such suit as may be reasonably requested by Adamas; provided that Adamas shall promptly reimburse all reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by Forest in connection with such cooperation. In respect of any enforcement action brought by Adamas pursuant to this Section 7.4(c), Adamas shall (i) keep Forest reasonably informed regarding Adamas’ actions with respect to the enforcement of the Adamas Patent Rights or Adamas Know-How in respect of such Adamas IP Infringement Claim and (ii) promptly provide Forest

with copies of all documents and other materials filed by any party to such enforcement action with the court before which such enforcement action is pending. Adamas' step-in rights to initiate suit under this Section 7.4(c) with respect to the [*] shall [*].

(d) Restrictions on Enforcement. Notwithstanding anything herein to the contrary, if (A) the enforcing Party's intended position in any enforcement action with respect to an Adamas IP Infringement Claim or settlement thereof under Section 7.4(b) or 7.4(c), in either case, would be reasonably expected to have a material adverse effect on the non-enforcing Party's interest in and rights to the Adamas Intellectual Property (including the licenses granted hereunder), or the Commercialization of the Products or in the case of [*], other products that [*] in the Field in the non-enforcing Party's respective territory and (B) the non-enforcing Party notifies the enforcing Party of its objection to such enforcement position, the Parties shall meet and discuss the non-enforcing Party's objection in good faith and use reasonable efforts to determine a mutually agreeable enforcement position, provided that if the Parties fail to agree and the non-enforcing Party maintains its objection, [*]. Notwithstanding the foregoing sentence, this Section 7.4(d) shall [*].

(e) Conduct of Certain Actions; Costs. The Party initiating suit with respect to an Adamas IP Infringement Claim shall, subject to Sections 7.4(b) and 7.4(d), have the sole and exclusive right to select counsel for, and otherwise control, any suit initiated by it pursuant to Section 7.4(b) or 7.4(c). The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Sections 7.4(b) and 7.4(c), including the fees and expenses of the counsel selected by it. The non-initiating Party shall have the right to participate, but not control, and be represented in, any such suit by its own counsel at its own expense.

(f) Recoveries. Any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Party that assumes control over enforcing any Adamas IP Infringement Claim shall be allocated between the Parties as follows:

(i) first, the Party that assumes control over enforcing such Adamas IP Infringement Claim shall retain an amount equal to its actual reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred in pursuing such Adamas IP Infringement Claim;

(ii) second, to the extent the remaining amount is sufficient, the Party that assumes control over enforcing such Adamas IP Infringement Claim shall promptly pay to the other Party the other Party's actual reasonable, documented, out-of-pocket expenses

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(including reasonable counsel fees and expenses) actually and reasonably incurred in connection with enforcement of such Adamas IP Infringement Claim, to the extent not paid already pursuant to Section 7.4(b) or 7.4(c), or 7.11(b) as applicable; and

(iii) third, any remaining amount recovered shall be allocated between the Parties as follows: (A) with respect to any amounts related to FDC Products, other than Proprietary Non-Donepezil FDC Products, [*] to Forest and [*] to Adamas, (B) with respect to any amounts related to ER Products or Other Products, [*] to Forest and [*] to Adamas, and (C) with respect to any amounts related to Proprietary Non-Donepezil FDC Products, [*] to Forest and [*] to Adamas.

7.5 Enforcement of Joint Intellectual Property. [*] shall have the sole right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect or otherwise enforce and defend the Joint Intellectual Property with respect to any infringement of or unauthorized use or misappropriation of such Joint Intellectual Property anywhere in the world (including in connection with a Paragraph IV Claim or foreign equivalent); provided, however, that [*] shall not enforce the Joint Intellectual Property outside the Territory against (a) [*] or its Affiliates or (b) [*] or its Affiliates' respective (sub)licensees of a Product with respect to their activities with respect to any Product. [*] shall execute such legal papers and cooperate in the enforcement of any such suit against a Third Party as may be reasonably requested by [*]; provided that [*] shall promptly reimburse all reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by [*] in connection with such cooperation.

7.6 Patent Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any challenge of invalidity or unenforceability by any Third Party against an Adamas Memantine Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding (each, an "Invalidity Claim"). Adamas and Forest will cooperate through

the JIPWG with respect to developing a strategy for the defense of any Invalidity Claim. [*] shall have the first right, but not the obligation, to defend against any such action against an Adamas Memantine Patent Right in the Territory, in its own name, and the costs of any such defense shall be at [*] expense; provided that [*] shall have the right to review and comment on the documentation, filings and communications related to such defense and, provided further that, [*] shall [*] [*] reasonable proposals or comments with respect to such documentation, filings and communications; and [*] shall [*] Adamas' proposals or comments [*]. [*], upon request of [*], agrees to join in any such action and to cooperate reasonably with [*]; provided that [*] shall promptly reimburse all reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by [*] in connection with such cooperation. [*], if [*] does not defend against any such action involving such Adamas Memantine Patent Right within [*] of a request from [*] to do so, then [*] shall have the right, but not the obligation, to defend such action and any such defense shall be at [*] expense. [*], upon request of [*], agrees to join in any such action and to cooperate reasonably with [*], provided that [*] shall promptly reimburse all reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by [*] in connection with such cooperation. [*] right to defend against any such action involving an Adamas Memantine Patent Right under

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this Section 7.6 shall [*]. Notwithstanding the foregoing, if (A) the defending Party's intended position in the defense of any Invalidity Claim would be reasonably expected to have a material adverse effect on the non-defending Party's interest in and rights to the Adamas Intellectual Property (including the licenses granted hereunder) or the Commercialization of the Products in the Field in the non-defending Party's respective territory and (B) the non-defending Party notifies the defending Party of its objection to such intended position with respect to the defense of such Invalidity Claim, the Parties shall meet and discuss the non-defending Party's objection in good faith and use reasonable efforts to determine a mutually agreeable position, provided that if the Parties fail to agree and the non-defending Party maintains its objection, [*] in the defense of such Invalidity Claim. This Section 7.6 shall apply *mutatis mutandis* with respect to the Adamas Patent Rights that are not Adamas Memantine Patent Rights if the Invalidity Claim arises in connection with the enforcement of an Adamas IP Infringement Claim pursuant to Section 7.4 or an Adamas Paragraph IV Claim pursuant to Section 7.11, with the Party who is controlling such enforcement having the first right to defend against such Invalidity Claim.

7.7 Claimed Infringement.

(a) If a Third Party asserts that a Patent Right or other intellectual property right owned or otherwise controlled by it is infringed by the Development, Manufacture or Commercialization of a Product, excluding Namenda (a "Third Party Infringement Claim"), the Party first made aware of such a claim shall promptly provide the other Party written notice of such claim along with the related facts in reasonable detail.

(b) As between the Parties, Forest shall have the sole right, but not the obligation, to defend and resolve any Third Party Infringement Claim that is asserted against Forest or any of its Affiliates or Sublicensees (including, subject to Section 7.7(e), by entering into any settlement agreement with such Third Party); provided that the provisions of Section 7.4 shall govern the right to assert a counterclaim of infringement of any Adamas Patent Rights in connection with such defense, and the costs of any such defense or resolution shall be at Forest's expense (except as otherwise provided in ARTICLE X). If Forest is required, based on a final judgment in any such Third Party Infringement Claim against Forest or settlement thereof, to pay a royalty or other amount with respect to the Development, Manufacture or Commercialization of a Product in the Field in the Territory, such amounts may be offset as set forth in Section 6.4(c)(vii) with respect to such Product, as applicable.

(c) As between the Parties, Adamas shall have the sole right, but not the obligation, to defend and resolve any Third Party Infringement Claim that is asserted against Adamas or any of its Affiliates (including, subject to Section 7.7(e), by entering into any settlement agreement with such Third Party); provided that the provisions of Section 7.4 shall govern the right to assert a counterclaim of infringement of any Adamas Patent Rights in connection with such defense, and the costs of any such defense or resolution shall be at Adamas' expense (except as otherwise provided in ARTICLE X). [*]

(d) With respect to any Third Party Infringement Claim that is asserted against both Adamas or any of its Affiliates or (sub)licensees, on the one hand, and Forest or any of its Affiliates, on the other hand, Adamas and Forest shall cooperate through the JIPWG with respect to developing and coordinating a strategy for the defense of any such Third Party

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Infringement Claim (including, subject to Section 7.7(e), by entering into any settlement agreement with such Third Party) and shall use Commercially Reasonable Efforts to comply with any such strategy developed by the JIPWG; provided that each Party shall have the sole right to defend and resolve of any Third Party Infringement Claim that is asserted against it or its Affiliates at its discretion.

(e) Neither Party shall enter into a settlement with respect to a Third Party Infringement Claim without the prior consent of the other Party if (i) such settlement would adversely affect or diminish the rights and benefits of the other Party under this Agreement, or impose any new obligations or adversely affect any rights or obligations of the other Party under this Agreement or (ii) in connection with such settlement, a Party makes an admission regarding the infringement, validity or enforceability of such Third Party's Patent Rights that would be reasonably expected to have a material adverse effect on the Commercialization of the Products in the Field in the other Party's respective territory.

7.8 Patent Term Extensions. [*] seek patent term extensions or supplemental patent protection, including supplementary protection certificates, in the Territory in relation to the Products [*]. Adamas and Forest shall cooperate in connection with all such activities, and [*], its agents and attorneys will give due consideration to all timely suggestions and comments of [*] regarding any such activities; provided that [*].

7.9 Patent Marking. If reasonably requested by Adamas, with respect to the Adamas Patent Rights, Forest shall comply with the patent marking statutes in the Territory with respect to a Product that is sold in the Territory by Forest, its Affiliates or its Sublicensees.

7.10 Interpretation of Patent Judgments. If any claim in a patent under the Adamas Patent Rights, including any Adamas Memantine Patent Right, or Forest Patent Rights becomes the subject of a judgment, decree or decision of a court, tribunal, or other authority of competent jurisdiction in the Territory, which judgment, decree, or decision is or becomes final (there being no further right of review) and adjudicates the validity, enforceability, scope or infringement of the same, the construction of such claim in such judgment, decree or decision shall be followed thereafter in the Territory in determining whether a Product is subject to a royalty hereunder, not only as to such claim but also as to all other claims in the Territory to which such construction reasonably applies. If at any time there are two or more conflicting final judgments, decrees, or decisions with respect to the same claim, the decision of the higher tribunal shall thereafter control, but if the tribunals be of equal rank, then the final judgment, decree, or decision more favorable to such claim shall control unless and until the majority of such tribunals of equal rank adopt or follow a less favorable final judgment, decree, or decision, in which event the latter shall control.

7.11 Certification under Drug Price Competition and Patent Restoration Act.

(a) Notice. If a Party becomes aware of any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions (a "Paragraph IV Claim") claiming that any Adamas Patent Rights Covering a Product in the Field in the Territory are invalid or otherwise unenforceable, or that infringement of any Adamas Patent Right will not arise from the manufacture, use, import or sale of a Product by a Third Party in the Field in the

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Territory (a "Adamas Paragraph IV Claim"), such Party shall promptly notify the other Party in writing within five (5) Business Days after its receipt thereof.

(b) Control of Response; Recoveries. [*] shall have the first right, but not the obligation, to initiate and control patent infringement litigation for an Adamas Paragraph IV Claim; provided that the provisions of Section 7.6 shall govern the right to defend any challenge to the validity or enforceability of any Adamas Patent Right brought in connection with such action. Any suit by [*] shall be brought either in the name of Adamas or its Affiliate, the name of Forest or its Affiliate, or jointly by Forest, Adamas and their respective Affiliates, as may be required by the Law of the forum and [*] shall join any action brought by [*]

pursuant to this Section 7.11 if requested by [*], at [*] expense, and otherwise shall have the right to participate, at its sole expense, in such action. [*] shall execute such legal papers and cooperate in the prosecution of such suit as may be reasonably requested by [*]; provided that [*] shall promptly reimburse [*] reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by [*] in connection with such cooperation. In respect of any patent infringement litigation for such Adamas Paragraph IV Claim controlled by [*], [*] shall (i) keep [*] reasonably informed regarding [*] actions with respect to such action and (ii) promptly provide [*] with copies of all documents and other materials filed by any party to such infringement litigation for such Adamas Paragraph IV Claim with the court before which such infringement action is pending. [*] shall [*] reasonable proposals or comments with respect to such documents and materials; and [*] shall [*] reasonable proposals or comments. If [*] elects not to assume control over litigating any Adamas Paragraph IV Claim, [*] shall notify [*] as soon as practicable but in any event not later than [*] before the first action required to litigate such Adamas Paragraph IV Claim so that [*] may, but shall not be required to, assume sole control over litigating such Adamas Paragraph IV Claim using counsel of its own choice. Notwithstanding the foregoing, if [*] a patent infringement litigation for such Adamas Paragraph IV Claim pursuant to this Section 7.11(b) that [*] and [*], [*] litigation for such Adamas Paragraph IV Claim; provided, however, that [*] with respect to such Adamas Paragraph IV Claim based on considerations of [*] under this Agreement. Any suit by [*] shall be either in the name of Adamas or its Affiliate, the name of Forest or its Affiliate, or jointly by Forest, Adamas and their respective Affiliates, as may be required by the Law of the forum. [*] shall join any action brought by [*] pursuant to this Section 7.11 if requested by [*], at [*] expense, and otherwise shall have the right to participate, at its sole expense, in such action. [*] shall execute such legal papers and cooperate in the prosecution of such suit as may be reasonably requested by [*]; provided that [*] shall promptly reimburse all reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by [*] in connection with such cooperation. In respect of any patent infringement litigation for such Adamas Paragraph IV Claim for which [*] assumes control under this Section 7.11(b), [*] shall (1) keep [*] reasonably informed regarding [*] actions with respect to such action and (2) promptly provide [*] with copies of all documents and other materials filed by any party to such infringement litigation for such Adamas Paragraph IV Claim with the court before which such infringement action is pending. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 7.4(f) above. In the case of a conflict between this Section 7.11 and Section 7.4 with regard to any action covered by this Section 7.11, this Section 7.11 shall control.

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(c) Notwithstanding the foregoing, if (i) the litigating Party's intended position in any infringement litigation for an Adamas Paragraph IV Claim or settlement thereof under this Section 7.11 would be reasonably expected to have a material adverse effect on the non-litigating Party's interest in and rights to the Adamas Intellectual Property (including the licenses granted hereunder) or the Commercialization of the Products in the Field in the non-litigating Party's respective territory and (ii) the non-litigating Party notifies the litigating Party of its objection to such position, the Parties shall meet and discuss the non-litigating Party's objection in good faith and use reasonable efforts to determine a mutually agreeable position, provided that if the Parties fail to agree and the non-litigating Party maintains its objection, [*] with respect to such Adamas Paragraph IV Claim. Notwithstanding the foregoing sentence, this Section 7.11(c) shall [*].

7.12 Adamas Product Trademark Rights.

(a) Prosecution of Adamas Product Trademark Rights. [*] the prosecution and maintenance of the Adamas Product Trademark Rights in the Territory. [*] shall cooperate with [*] with respect to such prosecution and maintenance, subject to [*] reimbursement of [*] reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by [*] in connection with such cooperation. [*] shall have the right to review and comment on the documentation, filings and communications to or from the US Patent and Trademark Office (or any successor agency) (including reasonable access thereto) related to the Adamas Product Trademark Rights.

(b) Enforcement and Defense of Adamas Product Trademark Rights.

(i) Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Adamas Product Trademark Rights in the Territory and of any actual or threatened claim that the use of the Adamas Product Trademark Rights in the Territory infringes, dilutes, misappropriates, or otherwise violates the rights of any Third Party. Each Party agrees to cooperate fully with the other Party with respect to any enforcement action or defense commenced pursuant to this Section 7.12; provided that the Party controlling such enforcement action or defense shall reimburse the reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and expenses) actually and reasonably incurred by the

other Party in connection with such cooperation. Notwithstanding the foregoing, Forest shall have no obligation under this Section 7.12(b)(i) unless it elects to use the Adamas Product Trademark Rights.

(ii) Forest shall have the sole right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the Adamas Product Trademark Rights relating to a Product in the Field in the Territory. Any such suit by Forest shall be brought either in the name of Adamas or its Affiliate, the name of Forest or its Affiliate, or jointly by Forest, Adamas and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Adamas shall join such suit, if requested by Forest, and execute such legal papers and cooperate in the prosecution of such suit as may be reasonably requested by Forest; provided that Forest shall promptly reimburse Adamas' reasonable, documented, out-of-pocket expenses (including reasonable outside counsel fees and

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expenses) actually and reasonably incurred by Adamas in connection with such cooperation. [*] any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party as a result of Forest's enforcement of the Adamas Product Trademark Rights pursuant to this Section 7.12(b).

(c) Third Party Claims. [*] defend against any alleged, threatened, or actual claim by a Third Party that the use or registration of the Adamas Product Trademark Rights in the Territory infringes, dilutes, misappropriates, or otherwise violates any Trademark Rights or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party in connection with such use of the Adamas Product Trademark Rights with respect to a Product in the Territory. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 7.4(f) above. [*] shall have the right to participate and be in, but not control, any such suit [*] under this Section 7.12(c) by its own counsel at its own expense. In the event that [*] does not take appropriate action to defend and resolve such suit [*], which suit is covered by this Section 7.12(c), then [*] may, in its discretion, provide [*] with notice of [*] intent to defend such suit. If [*] provides such notice and [*] does not initiate or continue, as applicable, the defense of such suit within [*] after receipt of such notice, then [*] shall have the right to defend and resolve such suit.

7.13 Privileged Communications. In furtherance of this Agreement, it is expected that Forest and Adamas will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with ARTICLE VIII, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Adamas and Forest, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Adamas Patent Rights and Forest Patent Rights. In the event of any litigation (or potential litigation) subject to this ARTICLE VII, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense agreement.

ARTICLE VIII

CONFIDENTIAL INFORMATION

8.1 Treatment of Confidential Information. During the Term and for [*] thereafter, each Party shall maintain Confidential Information (as defined in Section 8.2) of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents, directors, officers, employees, consultants, subcontractors, licensees, partners, Affiliates and advisors (collectively, "Agents") under obligations of confidentiality) or use it for any purpose other than in connection with the Development, Manufacture or Commercialization of Products in accordance with this Agreement, and each Party shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized use and disclosure of such Confidential Information by any of its Agents, which efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information. Each Party will be responsible for a

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breach of this ARTICLE VIII by its Agents. Forest may disclose Confidential Information of Adamas, and Adamas may disclose Confidential Information of Forest (including any [*]) (a) to Governmental Authorities in order to respond to inquiries, requests or investigations by Governmental Authorities and (b) subject to Section 4.2(f), otherwise to the extent reasonably necessary in order to fulfill its obligations or exercise its rights under Section 4.2(f) and 4.5 under this Agreement (but for clarity, except pursuant to [*] use Confidential Information of [*] for purposes related to [*]). In addition, Forest may disclose Confidential Information of Adamas (x) to the extent reasonably necessary or useful to obtain or maintain INDs or Regulatory Approvals for any Product consistent with Forest's rights under this Agreement; (y) to outside consultants, scientific advisory boards, managed care organizations, and non-clinical and clinical investigators to the extent reasonably necessary or reasonably useful to Develop, Manufacture or Commercialize any Product in a manner consistent with Forest's rights under this Agreement; or (z) to the extent reasonably useful to Develop, Manufacture or Commercialize any Product in a manner consistent with Forest's rights under this Agreement. With respect to any disclosure of the other Party's Confidential Information pursuant to this Section 8.1, each Party shall obtain the same confidentiality obligations from any Third Parties (excluding Governmental Authorities) to which it discloses the Confidential Information of the other Party as it obtains with respect to its own similar types of confidential information.

8.2 Confidential Information. "Confidential Information" means all trade secrets or other proprietary information, know-how, including any proprietary data and materials (whether or not patentable or protectable as a trade secret), regarding a Party's or its Affiliate's or licensor's technology, products, business, financial status or prospects or objectives regarding the Products that is disclosed by a Party to the other Party; provided, that, notwithstanding the foregoing, the [*] shall be the Confidential Information of [*]. All information disclosed prior to the Effective Date by either Party or its Affiliates pursuant to the confidentiality agreement between Adamas and Forest Parent dated as of [*], as amended through the Effective Date (the "Confidentiality Agreement") shall be deemed "Confidential Information" of such Party. For clarity, all data and information regarding Products generated after the Effective Date by Forest or by Third Parties on behalf of Forest, its Affiliates or their Sublicensees, including Forest Know-How [*] shall be deemed "Confidential Information" of Forest, and all data and information regarding Products generated after the Effective Date by Adamas or by Third Parties on behalf of Adamas, its Affiliates or their (sub)licensees [*], including Adamas Know-How, shall be deemed "Confidential Information" of Adamas. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(a) was known by the receiving Party or its Affiliate prior to disclosure by the disclosing Party or its Affiliate hereunder or under the Confidentiality Agreement (as evidenced by the receiving Party's or such Affiliates' written records or other competent evidence);

(b) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party without any violation of any obligation to the other Party; provided that the foregoing exclusion [*]; or

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(c) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Agents; or

(d) is independently developed by or for the receiving Party without reference to or reliance upon the disclosing Party's Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

Notwithstanding the foregoing, the receiving Party may disclose the disclosing Party's Confidential Information if it is required to be disclosed to comply with applicable Laws, to defend or prosecute litigation or to comply with governmental regulations or the regulations or requirements of any stock exchange, provided that the receiving Party promptly provides prior notice of such disclosure to the other Party and uses Commercially Reasonable Efforts to avoid or minimize the degree of such disclosure.

8.3 Registration, Filing and Disclosure of the Agreement. The terms of this Agreement are confidential and shall not be disclosed by either Party except pursuant to this Section 8.3 and Section 8.5. To the extent a Party determines in good faith that it is required by applicable Law to publicly file, register or notify this Agreement with a Governmental Authority, including public filings pursuant to securities Laws or securities exchange rules, such disclosing Party shall provide the proposed redacted form of this Agreement to the other Party with a reasonable amount of time prior to filing or disclosure for the other Party to review and approve such draft, such approval not to be unreasonably conditioned, withheld or delayed. The Party making such filing, registration,

notification or disclosure shall submit this Agreement in a manner consistent with the agreed redaction and shall use Commercially Reasonable Efforts to seek confidential treatment for the redacted terms, to the extent such confidential treatment is applicable and reasonably available consistent with applicable Law. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification. In the event that Forest consents to any disclosure of the terms of this Agreement that would otherwise be prohibited under this Section 8.3, such disclosure must be pursuant to obligations of confidentiality no less stringent than set forth in this Agreement.

8.4 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of clinical trials of pharmaceutical products. Accordingly, subject to this Section 8.4 and coordination through designated representatives of each Party, each Party shall be free to publicly disclose the results of clinical trials that it sponsors involving Products, subject to [*] prior review by the other Party for protection of its Confidential Information, in a manner consistent with all applicable Laws. For purposes of this Section 8.4, [*] shall be deemed the sponsor of any clinical trial conducted under the Development Plan. In addition, if a Party intends to publish articles in scientific or medical journals or to make public presentations of the results of such clinical trials, such Party shall provide to the other Party through the designated representatives of each Party at its earliest opportunity with any such proposed abstracts, manuscripts or summaries of presentations. The Party receiving such abstract, manuscript or summary shall respond promptly through its designated representative, and in any event no later than [*] after receipt of such proposed publication or presentation, with its comments, including any Confidential Information of such Party to be removed prior to publication or presentation. The Party making such publication or presentation agrees to remove

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any Confidential Information identified by the other Party as to which it does not have a right of disclosure hereunder, and will give due regard to comments furnished by such other Party and such comments shall not be unreasonably rejected. All publications involving Products made pursuant to this Section 8.4 shall be in accordance with any guidelines or strategies promulgated by the JDC and shall include appropriate acknowledgement consistent with standard scientific practice of any contributions of each Party to the results being publicly disclosed (including acknowledgement to Adamas with respect to the design of DM104, DM105, DM303, and DM304). Notwithstanding the foregoing, [*] publicly disclose the results of clinical trials that [*] compliance with any guidelines or strategies promulgated by the JDC.

8.5 Press Releases and Other Disclosures. The Parties hereby each approve the form of joint press release set forth in Schedule 8.5 and shall cooperate in the release thereof as soon as practicable after the Effective Date. The Parties also recognize that each Party may from time to time desire to issue additional press releases and make other public statements or public disclosures regarding the subject matter of this Agreement. In such event, the Party desiring to issue an additional press release or make such a public statement or disclosure shall provide the other Party with a copy of the proposed press release, statement or disclosure for review and approval in advance (except that neither Party shall have any obligation to disclose Confidential Information except to the extent required or permitted pursuant to this ARTICLE VIII). No other public statement or public disclosure concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 8.5, then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Section 8.5, Schedule 8.5 or of this ARTICLE VIII, a Party may (a) disclose the existence and terms of this Agreement where required, as reasonably determined by the disclosing Party, by applicable Law, by applicable stock exchange regulation or by order or other ruling of a competent court, (b) disclose the existence and terms of this Agreement under obligations of confidentiality to agents, advisors and contractors, and to potential agents, advisors, and contractors, and (c) publicly announce any of the matters set forth in Schedule 8.5, provided that the announcing Party provides the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text. In an effort to facilitate the Parties' disclosure of the existence and terms of this Agreement to certain Third Parties (under obligations of confidentiality at least as strict as those contained in this Article VIII) not otherwise permitted by this Section 8.5, the Parties agree to use the following staged process in disclosing the existence and terms of this Agreement to existing and potential acquirers, partners and investors. Each Party may initially disclose to potential acquirers, partners and investors (under obligations of confidentiality) an agreed redacted version of this Agreement, which the Parties shall jointly prepare and use good faith efforts to agree to promptly after the Effective Date; provided, that if either Party seeks to disclose the existence and terms of this Agreement to potential acquirers, partners and investors prior to the Parties' agreeing on a redacted version of this Agreement in a manner not permitted by this Section 8.5, [*]. Following disclosure of the agreed redacted version of this Agreement to any potential acquirers, partners and investors, if such potential acquirers, partners and investors proceed to an advanced stage of diligence and evaluation of the applicable Party (and in any event after the execution of

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such transaction), subject to providing the other Party with [*] prior written notice (which such notice shall include the name of such potential acquirer, partner or investor, provided that the other Party agrees in writing to maintain the confidentiality of the fact that such Person is a potential acquirer, partner or investor of such Party, and to not use the knowledge of such fact for any purpose other than maintaining an internal record as to which Third Party has had access to an unredacted version of this Agreement), such Party shall have the right to disclose an unredacted version of the Agreement to such Third Party.

8.6 **Product Information.** Adamas recognizes that by reason of, *inter alia*, Forest's status as an exclusive licensee pursuant to the grants under Section 2.1(a), Forest has an interest in Adamas' retention in confidence of the Product Information. Accordingly, during the Term, except pursuant to its exercise of rights under Section 4.2(f), Adamas shall maintain the Product Information in confidence, and shall not disclose, divulge or otherwise communicate the Product Information to others (except for its Agents under obligations of confidentiality) or use it for any purpose other than in connection with the Development, Manufacture or Commercialization of Products in accordance with this Agreement, and Adamas shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized use and disclosure of the Product Information by any of its Agents, which efforts shall be at least as diligent as those generally used by Adamas in protecting its own confidential and proprietary information, except to the extent (a) such disclosure would be permitted under clause (a) or (b) of Section 8.1 or the last sentence of Section 8.2 if the Product Information were Confidential Information of Forest or (b) the Product Information becomes published or generally known to the public through no fault or omission on the part of Adamas or its Agents.

ARTICLE IX **REPRESENTATIONS, WARRANTIES AND COVENANTS**

9.1 **Adamas' Representations.** Except as set forth on Schedule 9.1, Adamas hereby represents and warrants as of the Effective Date as follows:

(a) Adamas has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Adamas. Adamas has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of Forest, this Agreement constitutes a legal, valid and binding obligation of Adamas, enforceable against Adamas in accordance with its terms.

(b) The execution and delivery of this Agreement by Adamas and the performance by Adamas contemplated hereunder will not violate any US Law or, to Adamas' knowledge, any Law of any Governmental Authority outside the US.

(c) Neither the execution and delivery of this Agreement nor the performance hereof by Adamas requires Adamas or any of its Affiliates to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution, delivery and performance by Adamas or any of its Affiliates will not result in the breach of or

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give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Adamas or any of its Affiliates may be a party except any that would not, individually or in the aggregate, reasonably be expected to adversely affect Forest's rights under this Agreement or the ability of Adamas to perform its obligations under this Agreement.

(d) To Adamas' knowledge, there is no actual or threatened infringement by a Third Party of any of the Adamas Patent Rights or Adamas Product Trademark Rights in the Territory, or any other actual infringement or threatened infringement in the Territory by a Third Party that would adversely affect Forest's rights under this Agreement. To Adamas' knowledge, the practice of the

Adamas Manufacturing Know-How or the Development, Manufacture, use, sale, offer for sale or importation by Forest of (i) a Memantine-Donepezil FDC Product (but only with respect to the combination of Memantine and Donepezil as active ingredients in such Product and not with respect to any aspect of such Product other than the combination of such active ingredients, such as the formulation or manufacturing process of such Product or its components) or (ii) the Initial FDC Product, in each case in accordance with this Agreement, does not and will not infringe or constitute a misappropriation or other violation of the rights of any Third Party in the Territory existing as of the Effective Date to which Forest does not have a license as of the Effective Date. To Adamas' knowledge, the issued patents encompassed within Adamas Patent Rights are valid and enforceable patents and no Third Party has challenged the validity or enforceability of such patents (including through the institution or written threat of institution of interference, nullity, revocation or similar invalidity proceedings before the US Patent and Trademark Office), and Adamas has not received a written opinion of counsel setting forth a reasonable basis for such a claim by a Third Party.

(e) The Adamas Patent Rights and Adamas Product Trademark Rights have been filed and are being maintained in accordance with the procedures of the respective offices in which they are filed in the Territory, including the US Patent and Trademark Office, and all applicable fees have been paid.

(f) To Adamas' knowledge, each of the Adamas Patent Rights properly identifies each and every inventor of the claims thereof as determined in accordance with Law in the Territory.

(g) To Adamas' knowledge, each Person who has or has had any ownership rights in or to any Adamas Patent Rights, Adamas Know-How or the Adamas Product Trademark Rights has assigned and has executed an agreement assigning its entire right, title and interest in and to such Adamas Patent Rights, Adamas Know-How or Adamas Product Trademark Rights, as the case may be, to Adamas.

(h) Schedule 1.7 includes: (i) to Adamas' knowledge, a complete and correct list of all pending or issued Adamas Patent Rights, and (ii) a complete and correct list of all pending or issued Adamas Memantine Patent Rights, in each case Controlled by Adamas or its Affiliates as of the Effective Date.

(i) Adamas is the sole and exclusive legal and beneficial owner of, and Controls, all the Adamas Patent Rights and all Adamas Product Trademark Rights, in each case,

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that exist as of the Effective Date and is entitled to grant the licenses and other rights granted by Adamas herein. To Adamas' knowledge, all assignments to Adamas of ownership rights relating to the Adamas Patent Rights, Adamas Know-How and the Adamas Product Trademark Rights are valid and enforceable. Adamas has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Adamas Intellectual Property and the Adamas Product Trademark Rights in the Territory or otherwise in a manner that conflicts with any license, assignment or other rights granted to Forest hereunder.

(j) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending against or, to Adamas' knowledge, threatened against Adamas in the Territory in connection with any Adamas Patent Rights, Adamas Know-How, Adamas Product Trademark Rights or against or relating to the transactions contemplated by this Agreement.

(k) To Adamas' knowledge, the conception, development and reduction to practice of (i) the Adamas Patent Rights and (ii) the Adamas Know-How existing as of the Effective Date, in each case (clause (i) and (ii)) have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person.

(l) The Adamas Patent Rights and Adamas Know-How (i) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof; and (ii) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. part 401 (the "Bayh-Dole Act").

(m) No payments to Third Parties for rights under Third Party Technology would be owed with respect to the Adamas Intellectual Property as a result of the Parties' activities hereunder under agreements existing as of the Effective Date to which

Adamas or any of its Affiliates is a party.

(n) All written information, documentation and other materials furnished or made available by Adamas upon the request of Forest during Forest's period of diligence prior to the Effective Date are true, complete and correct copies of what they purport to be (as redacted for purposes of confidentiality).

(o) To Adamas' knowledge, all Development activities conducted by Adamas with respect to the Products prior to the Effective Date have been and are being conducted in material compliance with experimental protocols, procedures and controls pursuant to generally accepted professional scientific standards, and applicable Law, including applicable requirements of "good laboratory practices" and "good clinical practices," as applicable, as defined by the FDA. Adamas has not received any written notices from the FDA or any other Regulatory Authority requiring the termination, suspension or material modification of any clinical trials of the Products that have been or are currently being conducted by Adamas.

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(p) Adamas has prepared, maintained and retained all Regulatory Filings for the Products in accordance in all material respects with all applicable Laws.

(q) Adamas has obtained all required consents from any Person (including any Third Party manufacturer) necessary to transfer the Adamas Manufacturing Know-How to Forest.

(r) There are no Trademark Rights (other than the corporate names of Adamas) associated with any Product under Development by Adamas other than the Adamas Product Trademark Rights.

(s) Neither Adamas nor, to the knowledge of Adamas, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state Law.

(t) Schedule 9.1(t) sets forth a complete list of all of the material contracts relating to the Products to which Adamas (or its Affiliate) is a party.

(u) Adamas has disclosed or provided access to Forest, as redacted for purposes of confidentiality, all material information known to Adamas regarding Adamas' Development, Manufacturing and Commercialization of the Products in the Field in the Territory, including all regulatory information regarding the Products in the Field in the Territory (including all adverse information with respect to the safety and efficacy of the Products) known to Adamas or its Affiliates as of the Effective Date and made available to Forest, as redacted for purposes of confidentiality, a full and complete copy of the End of Phase II Meeting Minutes, which minutes include all approval requirements for the NDA for the Initial FDC Product specified by the FDA at or in connection with the End of Phase II Meeting.

(v) Adamas has no Affiliates as of the Effective Date other than Adamas India, Ltd. and Adamas Singapore, Ltd.

(w) Adamas has disclosed to Forest all material non-public information known to Adamas and its Affiliates with respect to the safety and efficacy of each Product under development by Adamas as of the Effective Date that is not generally related to pharmaceutical products that contain Memantine or Donepezil as an active pharmaceutical ingredient.

(x) Adamas has made available to Forest all material regulatory documentation owned or possessed by Adamas regarding or related to the Products in the Field in the Territory. Adamas has prepared, maintained or retained all such material regulatory documentation required to be maintained or reported pursuant to and in accordance with the applicable requirements of "good laboratory practices" and "good clinical practices," as applicable, as defined by the FDA, to the extent required, and applicable Law, and such regulatory documentation does not contain any materially false or misleading statements.

9.2 Forest's Representations. Except as set forth in Schedule 9.2, Forest hereby represents and warrants as of the Effective Date as follows:

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(a) Forest has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Forest. Forest has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound to authorize such execution, delivery and (subject to obtaining all necessary governmental approvals with respect to the continued Development and Commercialization of Products) performance. Assuming due authorization, execution and delivery on the part of Adamas, this Agreement constitutes a legal, valid and binding obligation of Forest, enforceable against Forest in accordance with its terms.

(b) The execution and delivery of this Agreement by Forest and Forest's performance hereunder will not violate (subject to obtaining all necessary governmental approvals with respect to the continued Development, Manufacture and Commercialization of Products) any Law in the Territory or, to Forest's knowledge, any Law of any Governmental Authority outside the Territory.

(c) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Forest, threatened against Forest in connection with or relating to the transactions contemplated by this Agreement.

(d) Neither the execution and delivery of this Agreement nor the performance hereof by Forest requires Forest or any of its Affiliates to obtain any permit, authorization or consent from any Governmental Authority (subject to obtaining all necessary governmental approvals with respect to the continued Development and Commercialization of Products) or from any other Person, and such execution, delivery and performance by Forest or any of its Affiliates will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Forest or any of its Affiliates may be a party, except any that would not, individually or in the aggregate, reasonably be expected to adversely affect Adamas' rights under this Agreement or the ability of Forest to perform its obligations under this Agreement.

(e) The copy of [*] the consummation of the transaction contemplated by this Agreement attached hereto as Schedule 9.2(e) is a true and correct copy of such [*].

(f) Neither Forest nor, to the knowledge of Forest, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state Law.

(g) To Forest's knowledge, the Development, Manufacture, use, sale, offer for sale or importation by Forest of a Memantine-Donepezil FDC Product (but only with respect to the combination of Memantine and Donepezil as active ingredients in such Product and not with respect to any aspect of such Product other than the combination of such active ingredients, such as the formulation or manufacturing process of such Product or its components) does not and

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will not infringe or constitute a misappropriation or other violation of the rights of any Third Party in the Territory to which Forest does not have a license as of the Effective Date.

(h) The [*] in a manner that, as compared to the [*], has an adverse effect on the rights of Adamas hereunder (including the scope of the Patent Rights and Know-How that [*] under [*]). The [*], and [*], in each case in a manner that would have an adverse effect on such rights of Adamas.

(i) If and to the extent that [*], the scope of the intellectual property rights [*] that [*] to Develop, Manufacture and Commercialize [*] shall [*] intellectual property rights [*] to Develop, Manufacture and Commercialize [*].

9.3 Adamas Covenants. Adamas covenants and agrees during the Term that:

- (a) Adamas shall not grant to any Third Party any rights that would conflict with Forest's rights hereunder.
- (b) Adamas shall not assign, transfer, convey or otherwise encumber its right, title and interest in the Adamas Intellectual Property in a manner that conflicts with any rights or licenses granted to Forest hereunder.
- (c) Adamas shall notify Forest if any of its directors or officers (or any of its employees, agents or subcontractors if such employee, agent or subcontractor is or was involved in the Development of any Product on behalf of Adamas or its Affiliates) is convicted of any crime or engaged in any conduct that results, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state Law.

9.4 Forest Covenants. Forest covenants and agrees during the Term that:

- (a) Forest shall not grant to any Third Party any rights that would conflict with Adamas' rights hereunder (including under Schedule 11.6 upon a reversion of the FDC Products).
- (b) Forest shall not assign, transfer, convey or otherwise encumber its right, title and interest in the Forest Intellectual Property in a manner that conflicts with any rights granted to Adamas hereunder (including under Schedule 11.6 upon a reversion of the FDC Products).
- (c) Forest shall not [*] in a manner that would adversely affect the rights of Adamas hereunder (including under [*]).
- (d) Within [*] following the Effective Date, if requested by Adamas, Forest shall [*], other than [*], to the extent [*] are reasonably required by Adamas in order to [*], and Forest shall use Commercially Reasonable Efforts to [*].
- (e) Forest shall notify Adamas if any of its directors or officers (or any of its employees, agents or subcontractors if such employee, agent or subcontractor is or was involved in the Development of any Product for which Forest has a payment obligation to Adamas under

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this Agreement) is convicted of any crime or engaged in any conduct that results, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar Law.

9.5 Mutual Covenants. Each Party shall conduct, and shall use Commercially Reasonable Efforts to cause its contractors and consultants to conduct, all of their activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted, including applicable requirements of "good laboratory practices", "good clinical practices" and "good manufacturing practices", as applicable, as defined by the FDA.

9.6 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.

ARTICLE X INDEMNIFICATION

10.1 Indemnification in Favor of Adamas. Forest shall indemnify, defend and hold harmless the Adamas Parties from and against any and all Losses incurred, suffered or sustained by any of the Adamas Parties or to which any of the Adamas Parties becomes subject as a result of any Third Party claim, action, suit, proceeding, liability or obligation (collectively, "Third Party Claims") arising out of, relating to or resulting from:

- (a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Forest in this Agreement; or

(b) the Development, Manufacture or Commercialization of Products by or on behalf of Forest, its Affiliates or Sublicensees anywhere in the world at any time (including the conduct of Development activities by Adamas or its Affiliates pursuant to the Development Plan as directed by Forest); or

(c) any claim under any Transferable Contract, if transferred to Forest, arising from any act or omission by Forest or its Affiliates or Sublicensees that occurs on or after the date such Transferable Contract was assigned to Forest; or

(d) the negligence or willful misconduct of any of the Forest Parties (as hereinafter defined) in connection with Forest's performance of this Agreement; or

(e) any claim of product liability related to Products marketed, sold or otherwise Commercialized by or on behalf of Forest, its Affiliates or Sublicensees.

For purposes of this ARTICLE X, "Adamas Parties" means Adamas, its Affiliates and their respective licensors, agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.1 shall not apply to the extent that any Loss is the result of (i) a breach of this Agreement by Adamas or (ii) with respect to any Adamas Party, any negligence or willful misconduct of such Adamas Party.

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10.2 Indemnification in Favor of Forest. Adamas shall indemnify, defend and hold harmless the Forest Parties from and against any and all Losses incurred, suffered or sustained by any of the Forest Parties or to which any of the Forest Parties becomes subject, as a result of any Third Party Claim arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Adamas in this Agreement; or

(b) the Development, Manufacture or Commercialization of the Products by or on behalf of Adamas, its Affiliates, licensees or (sub)licensees anywhere in the world at any time (excluding the conduct of Development activities by Adamas or its Affiliates pursuant to the Development Plan, as directed by Forest); or

(c) any claim under any Transferable Contract, if transferred to Forest, arising from any act or omission by Adamas, its Affiliates, licensees or (sub)licensees that occurred before the date such Transferable Contract was assigned to Forest; or

(d) the negligence or willful misconduct of any of the Adamas Parties in connection with Adamas' performance of this Agreement; or

(e) any claim of product liability related to Products marketed, sold or otherwise Commercialized by or on behalf of Adamas, its Affiliates, licensees or (sub)licensees.

For purposes of this ARTICLE X, "Forest Parties" means Forest, its Affiliates and their respective licensors (including [*]), agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.2 shall not apply to the extent that any Loss is the result of (i) a breach of this Agreement by Forest, or (ii) with respect to any Forest Party, any negligence or willful misconduct of any Forest Party.

10.3 General Indemnification Procedures. Except as otherwise provided herein:

(a) A Person seeking indemnification pursuant to this ARTICLE X (an "Indemnified Party") (i) shall give prompt notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim (which, in no event, includes any claim by any Forest Party or any Adamas Party) in respect of which indemnity may be sought hereunder, (ii) shall give the Indemnifying Party such information with respect to any indemnified matter as the

Indemnifying Party may reasonably request, and (iii) shall not make any admission concerning such Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party or the failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby (and no admission required by applicable Law or legal process shall be deemed to result in prejudice). Except with respect to any Third Party Claim that is a Third Party Infringement Claim, the process for the defense of which shall be governed by Section 7.7,

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the Indemnifying Party shall have the right to assume and conduct the defense of such Third Party Claim, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party, only if such Indemnifying Party concedes that such Indemnified Party shall be indemnified from and against such Third Party Claim pursuant to this ARTICLE X or if the Indemnified Party agrees in writing. Subject to the initial and continuing satisfaction of the terms and conditions of this ARTICLE X, the Indemnifying Party shall have full control of such Third Party Claim, including settlement negotiations and any legal proceedings. If the Indemnifying Party does not assume the defense of such Third Party Claim in accordance with this Section 10.3, the Indemnified Party may defend the Third Party Claim. If both Parties are Indemnifying Parties with respect to the same Third Party Claim (other than Third Party Claims that are also Third Party Infringement Claims, which are governed by Section 7.7), the Parties shall determine by mutual agreement, within twenty (20) days following their receipt of notice of commencement or assertion of such Third Party Claim (or such lesser period of time as may be required to respond properly to such claim), which Party shall assume the lead role in the defense thereof. Should the Indemnifying Parties be unable to mutually agree on which of them shall assume the lead role in the defense of such Third Party Claim, both Indemnifying Parties shall be entitled to participate in such defense through counsel of their respective choosing.

(b) Any Indemnified Party or Indemnifying Party not managing the defense of a Third Party Claim shall have the right to participate in (but not control), at its own expense, the defense. The Indemnifying Party managing the defense shall not be liable for any litigation cost or expense incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of such Indemnifying Party.

(c) The Indemnifying Party shall not consent to a settlement of, or the entry of any judgment against an Indemnified Party arising from any such Third Party Claim to the extent such Third Party Claim involves equitable or other non-monetary relief from the Indemnified Party. No Party shall, without the prior written consent of the other Party or the Indemnified Party, enter into any compromise or settlement that commits the other Party or the Indemnified Party to take, or to forbear to take, any action.

(d) The Parties shall cooperate in the defense or prosecution of any Third Party Claim and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith; provided, however, that the Indemnifying Party shall reimburse the Indemnified Party for any reasonable, documented, out-of-pocket expenses actually and reasonably incurred in connection with any such cooperation.

(e) Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this ARTICLE X, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the Indemnifying Party.

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(f) The Parties agree and acknowledge that the provisions of this ARTICLE X represent the Indemnified Party's exclusive recourse for any Losses incurred, suffered or sustained by such Indemnified Party arising out of, relating to or resulting from any Third Party Claims for which indemnification is provided to the Indemnified Party under this ARTICLE X.

10.4 Insurance. During the Term and thereafter for so long as a Third Party Claim may be brought for which Forest must indemnify Adamas pursuant to Section 10.1, or for which Adamas must indemnify Forest pursuant to Section 10.2, each Party shall obtain or maintain, at its sole cost and expense, product liability insurance for the Products in amounts that are reasonable and customary in the pharmaceutical industry or, in case the case Forest, and Adamas following a Change of Control if Adamas' Acquirer is self insured, a comparable program of self-insurance. Without limiting the generality of the foregoing, each Party shall maintain comprehensive general liability insurance, including product liability insurance, to cover its activities and, unless its Affiliates and (sub) licensees maintain comparable coverage, the activities of its Affiliates and (sub)licensee, with respect to Products. Each Party shall provide satisfactory evidence of adequate insurance coverage to the other Party upon the request of such other Party prior to the Effective Date and, upon the written request of such other Party, concurrent with any renewal or replacement of such coverage.

10.5 No Consequential or Punitive Damages. EXCEPT IN THE CASE OF ANY BREACH OF SECTION 2.4 OR ARTICLE VIII OR AS OTHERWISE PROVIDED BELOW, NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, MILESTONES OR ROYALTIES, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.5 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT WITH RESPECT TO THIRD PARTY CLAIMS, OR REMEDIES TO A PARTY IN THE CASE OF INFRINGEMENT OR MISAPPROPRIATION OF ITS INTELLECTUAL PROPERTY RIGHTS OR CONFIDENTIAL INFORMATION BY THE OTHER PARTY (INCLUDING UNDER SECTION 3.1(D)), OR THE WILLFUL MISCONDUCT, INTENTIONAL BREACH OR FRAUD OF THE OTHER PARTY. NOTWITHSTANDING THE FOREGOING, IN THE EVENT THAT EITHER PARTY SEEKS LOST ROYALTY DAMAGES OR OTHER SIMILAR DAMAGES UNDER SECTION 6.3 OR 6.4 OF THIS AGREEMENT FROM THE OTHER PARTY ARISING FROM THE OTHER PARTY'S BREACH OF THIS AGREEMENT, INCLUDING SECTION 5.4, THE LIMITATION OF LIABILITY UNDER THIS SECTION 10.5 SHALL NOT APPLY TO SUCH DAMAGES IF THEY ARE ESTABLISHED, QUANTIFIABLE AND DIRECTLY ARISE FROM SUCH BREACH.

ARTICLE XI

TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE XI, shall continue in full force and effect, on a Product-by-Product basis until there is no remaining royalty obligation in the Territory with respect to such Product, at which time this Agreement shall expire in its entirety with respect to such Product. Upon expiration of this Agreement with respect to all Products,

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this Agreement shall be considered expired in its entirety. Upon expiration of this Agreement with respect to a Product, from that time forward, the licenses and other rights granted to Forest in Article 2 shall become fully paid-up and remain irrevocable with respect to such Product.

11.2 Termination Rights for FDC Products.

(a) If Forest has not paid to Adamas either of the Milestone Payments under Section 6.3(a)(i) (the Bioequivalence Milestone) or Section 6.3(a)(ii) (the Stability Milestone) by the earlier of (i) the achievement of the Acceptance Milestone or (ii) the Outside Milestone Date, then, if Adamas notifies Forest in writing of such failure to pay and Forest has not made this payment within [*] of receipt of such notice, this Agreement shall automatically terminate with respect to all FDC Products at the end of such [*] and the provisions of Section 11.6 below shall apply.

(b) If Forest elects to permanently cease its Development or Commercialization of the FDC Products in the Field in the Territory, Forest shall provide written notice to Adamas of its intent to do so ("Cessation Notice"). If such Cessation Notice is delivered prior to the expiration of the FDC Royalty Term, then upon delivery of such Cessation Notice, this Agreement shall automatically terminate as of the date of the Cessation Notice with respect to all FDC Products and the provisions of Section 11.6 below shall apply.

(c) In the event a Governmental Authority brings a suit, claim, action, investigation, or proceeding, whether judicial or administrative, challenging any of the rights granted, transferred, or assigned to either of the Parties under Article II of this Agreement as a violation of any Antitrust Laws (as defined below) ("Antitrust Action") and (i) the Governmental Authority issues an

order, decree, or ruling against Forest, which order, decree, or ruling is final and non-appealable or (ii) Forest enters into a consent decree with a Governmental Authority to resolve or settle such Antitrust Action; in any case, having the effect of permanently restraining, enjoining, or otherwise prohibiting Forest to Develop and Commercialize FDC Products, then Forest shall notify Adamas in writing of such requirement and, to the extent permitted by Laws, Adamas shall have the right to terminate this Agreement with respect to all FDC Products upon written notice to Forest and the provisions of Section 11.6 below shall apply. In such event, if Adamas is required to cooperate in connection with any investigation in connection therewith, either at Forest's request or as required by such Governmental Authority, then Forest shall reimburse Adamas for its out-of-pocket costs incurred in connection with such activities by Adamas, up to a maximum reimbursement amount of one million dollars (\$1,000,000). "Antitrust Law" means the Sherman Act, as amended, the Clayton Act, as amended, the Federal Trade Commission Act, as amended, and all other Laws that are designed or intended to prohibit, restrict, or regulate actions having the purpose or effect of monopolization or restraint of trade, significant impediments to or lessening of competition, or the creation or strengthening of a dominant position through acquisition of intellectual property rights, including the granting of licenses, assignment of patents, or transfer of an NDA or other regulatory filings.

11.3 Damages In Lieu of Termination for Cause. Except as expressly set forth in Section 11.4, Adamas may not terminate this Agreement by reason of a breach of this Agreement by Forest, but may instead bring a claim against Forest seeking damages or equitable relief (in accordance with the provisions of this Agreement), provided that Adamas first complies with the

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provisions of this Section 11.3, as Adamas' sole remedy for Forest's breach. In the event that Forest breaches this Agreement and Adamas desires to seek any such relief, Adamas shall give to Forest written notice requiring it to cure such breach, which notice shall specify the nature of the breach. If such breach is not cured within [*] after receipt of such notice (or within [*] in the case of a payment breach), Adamas shall be entitled (without prejudice to any of its other rights conferred on it by this Agreement or under applicable Law) to bring a claim against Forest for damages or equitable relief; provided, however, that if such breach is not capable of being cured within the stated period and the breaching Party uses Commercially Reasonable Efforts to cure such breach during such period and presents a mutually agreeable remediation plan for such breach, the cure period shall be extended for such period provided in the remediation plan, for a maximum of an additional [*], as long as Forest continues to use Commercially Reasonable Efforts to pursue the cure as provided in such remediation plan.

11.4 Termination for Cause. In the event of a material breach of this Agreement by a Party, the non-breaching Party may give the breaching Party notice requiring it to cure such default, which notice shall specify the nature of the breach. If such material breach is not cured within [*] after receipt of such notice (or [*] in the case of a payment breach), the non-breaching Party shall be entitled (without prejudice to any of its other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement (a) in the case of Forest as the non-breaching Party, in its entirety or with respect to one or more Products, or (b) in the case of Adamas, solely with respect to the FDC Products, solely prior to the Payment Date and solely in the case of a material breach of Forest's obligation to use Commercially Reasonable Efforts with respect to the Development of the FDC Products in the Field in the Territory under Section 4.1, in each case ((a) and (b)) by giving written notice to the breaching Party. If any breach that is the basis of a Party's termination under this Section 11.4 is not capable of being cured within the stated cure period and the breaching Party uses Commercially Reasonable Efforts to cure such breach during such period and presents a mutually agreeable remediation plan for such breach, this Agreement shall not terminate and the cure period shall be extended for such period provided in the remediation plan, for a maximum of an additional [*], as long as the breaching Party continues to use Commercially Reasonable Efforts to pursue the cure as provided in such remediation plan. In the event the breaching Party notifies the other Party that it disputes in good faith the existence of a material breach or a Party's use of Commercially Reasonable Efforts to cure such a breach, termination of this Agreement shall not be deemed to occur unless and until such dispute has been referred for resolution in accordance with Section 12.2, the applicable material breach of the Agreement or failure to make diligent efforts to cure such breach has been established by an arbitration thereunder and, if such breach can be cured by the payment of money or the taking of specific remedial actions, the defaulting Party does not pay the amount so determined to be due within [*] of receipt of the arbitration decision or otherwise diligently undertake and complete such remedial actions within the timeframe established by such arbitration decision. In the event of termination of this Agreement by either Party pursuant to this Section 11.4, the licenses and other rights granted to Forest (and all payment obligations to Adamas) hereunder shall remain in effect with respect to the ER Products and the Other Products and Section 11.6 shall apply with respect to the FDC Products. A Party's termination of the Agreement under this Section 11.4 shall not preclude such Party from pursuing any right or remedy it may have hereunder or at Law or in equity with respect to any breach of this Agreement, including with respect to seeking damages from the defaulting Party.

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11.5 Termination for Insolvency. This Agreement may be terminated by a Party upon written notice to the other Party if (a) the other Party shall make an assignment of substantially all of its assets for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; or (b) if there shall have been filed against the other Party any such *bona fide* petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or that remains undismissed or unstayed for a period of [*] or more; or (c) if the other Party by any act or omission shall indicate its consent to, approval of or acquiescence in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged or unstayed for a period of [*] or more; or (d) anything analogous to any of the foregoing occurs in any applicable jurisdiction. Termination shall be effective upon the date specified in such notice.

11.6 Effect of Termination; Accrued Rights and Obligations.

(a) Notwithstanding anything in this Agreement to the contrary, Adamas shall not have the right to terminate this Agreement with respect to ER Products or Other Products.

(b) In the event of termination of this Agreement with respect to the FDC Products, the provisions of Schedule 11.6 shall apply.

(c) In the event of a termination by Adamas under Section 11.2(c), Adamas shall pay to Forest an amount equal to the fair market value of the rights that revert to Adamas under this Section 11.6. In the event that the Parties are unable to reach agreement as to the fair market value of such rights within [*] of such a termination, the Parties shall select and agree upon a mutually acceptable independent Third Party expert who is neutral, disinterested and impartial, and has expertise in pharmaceutical valuations, to determine the fair market value of the rights that revert to Adamas under this Section 11.6, which determination shall be binding on the Parties and Adamas shall pay to Forest such amount within [*] after the determination is provided to both Parties. Forest shall have no obligation under this Section 11.6 (other than those set forth in this paragraph), and the rights and licenses granted to Adamas under this Section 11.6 (including those set forth in Schedule 11.6) shall not be effective, until such payment is made to Forest.

(d) Expiration or termination of this Agreement in its entirety for any reason shall not release either Party from any liability that, at the time of such termination, has already accrued or that is attributable to a period prior to such expiration or termination (including payment obligations accrued prior to the effective date of termination pursuant to ARTICLE VI) nor preclude either Party from pursuing any right or remedy it may have hereunder or at Law or in equity with respect to any breach of this Agreement. Notwithstanding the foregoing, the Parties agree that no Milestone Payment under Section 6.3 shall be due if the Milestone Event is not achieved or met prior to the date a notice of termination under this ARTICLE XI is provided by the terminating Party. It is understood and agreed that monetary damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching Party may be

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entitled to seek injunctive relief as a remedy for any such breach (including any breach of Section 2.4 by Adamas (or its Affiliates or (sub)licensees)).

11.7 Survival. The rights and obligations set forth in this Agreement shall survive the expiration or termination of this Agreement in its entirety only to the extent expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of [*] shall survive expiration or termination of this Agreement in its entirety for any reason.

ARTICLE XII

MISCELLANEOUS

12.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the internal laws of the State of New York, without regard to its conflicts of laws rules. Subject to Section 12.2, each Party (a) irrevocably submits to the exclusive jurisdiction in the US District Court for the Southern District of New York and any state court sitting in New York County, New York (collectively, the “Courts”), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement.

12.2 Dispute Resolution; Arbitration.

(a) Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement, either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Executives of each Party, for attempted resolution by good faith negotiations within [*] after such notice is received. In the event the Senior Executives do not resolve such dispute within the allotted [*], or a Party reasonably believes such matter will not be so resolved, either Party may seek to resolve the dispute through arbitration in accordance with Section 12.2(b). For clarity, a disagreement regarding the manner in which a Party exercises any of its consent or final decision-making rights under Section 4.2(b) is not a “dispute arising out of or relating to this Agreement” if such exercise was consistent with the terms of this Agreement.

(b) Arbitration

(i) Claims. Any claim, dispute, or controversy of whatever nature arising between the Parties out of or relating to this Agreement, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement (“Claim”) that is not resolved under Section 12.2(a) within the required [*] time period, shall be resolved by final and binding arbitration before a panel of three (3) experts with relevant industry experience (the “Arbitrators”). Each of Adamas and Forest shall promptly select one Arbitrator each, which selections shall in no event be made later than [*] after the notice of initiation of arbitration.

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The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Adamas and the Arbitrator chosen by Forest, but in no event later than [*] after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery, provided that the Arbitrators shall permit such discovery as he or she deems necessary to permit an equitable resolution of the dispute. The arbitration shall be administered by the Judicial Arbitration and Mediation Services (or its successor entity) (“JAMS”) under its rules of arbitration then in effect, except as modified in this Agreement (the “Rules”). The arbitration shall be held in Chicago, Illinois, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party.

(ii) Arbitrators’ Award. The Arbitrators shall, within [*] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

(iii) Costs. Each Party shall bear its own counsel fees, costs, and disbursements arising out of the arbitration described in this Section 12.2(b), and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to the arbitration; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses), or the fees and costs of the Arbitrators.

(iv) Compliance with this Agreement. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding.

(v) Injunctive or Other Equity Relief. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm (including a breach by Adamas or its Affiliate or (sub)licensee of Section 2.4), and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

(vi) Confidentiality of Proceedings. All arbitration proceedings and decisions of the Arbitrator under this Section 12.2 shall be deemed Confidential Information of both Parties under ARTICLE VIII.

12.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder shall operate as a waiver of any right, power or privilege by such Party. No

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waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

12.4 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.4 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to Forest shall be addressed to:

Forest Laboratories Holdings Limited
Cumberland House
9th Floor
1 Victoria Street
Hamilton HM 11, Bermuda
Attention: Chairman
Facsimile: [*]

with a copy to:

Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022
Attention: General Counsel
Facsimile: [*]

Notices to Adamas shall be addressed to:

Adamas Pharmaceuticals, Inc.
2200 Powell Street, Suite 220
Emeryville, CA 94608
Attention: Chief Financial Officer
Facsimile: [*]

with a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Attention: Robert L. Jones, Esq.

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Facsimile: 650-849-7400

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.5 Entire Agreement. This Agreement (including Schedules) contains the complete understanding of the Parties with respect to the Development and Commercialization of Products and supersedes all prior understandings and writings between the Parties relating to such subject matter. In particular, and without limitation, it supersedes and replaces the Confidentiality Agreement and any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date.

12.6 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event, the Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

12.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred, whether by operation of law or otherwise, by either Party without the consent of the other Party; provided, however, that (a) either Party may, without such consent, assign this Agreement or any of its rights or obligations hereunder to any of its respective Affiliates, provided that such Party shall remain jointly and severally liable with such Affiliate in respect of all obligations so assigned and such Affiliate has acknowledged and confirmed in writing that effective as of such assignment or other transfer, such Affiliate shall be bound by this Agreement as if it were a party to it as and to the identical extent applicable to the transferor; and (b) either Party may, without such consent, assign this Agreement, including its rights and obligations hereunder, to any successor in interest by way of merger or acquisition, or other Change of Control (other than an asset sale, which shall be covered by clause (c)), including by operation of law, provided that such successor has acknowledged and confirmed in writing that effective as of such assignment or other transfer such successor shall be bound by this Agreement as if it were a party to it as and to the identical extent applicable to the applicable Party; and (c) a Third Party acquirer of all or substantially all of its assets of such Party; provided that such acquirer has acknowledged and confirmed in writing that effective as of such assignment or other transfer such acquirer shall be bound by this Agreement as if it were a party to it as and to the identical extent applicable to the applicable Party and such Party shall remain bound by [*] and ARTICLE VIII. Notwithstanding the foregoing, Adamas may assign its rights to payments to an entity owned by the stockholders of Adamas, which entity shall be a permitted assignee of such rights; provided, that no other rights of Adamas shall be assigned to such entity and that such assignment shall not affect the rights of Forest under this Agreement, including by the imposition of any lien or other encumbrance on any Adamas Intellectual Property. In the event Forest assigns or otherwise transfers any [*] or Forest

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Patent Rights to the extent necessary for the Development, Manufacture or Commercialization of the Products to any of its Affiliate or Third Party, Forest shall (A) condition such assignment or transfer upon an express written agreement of such Affiliates or Third Party to be bound by the terms and conditions of this Agreement to the same extent as Forest with respect to such [*] or Forest Patent Rights, as applicable (including terms and conditions of termination of this Agreement in accordance with Section 11.2); (B) be responsible for such Affiliate's or Third Party's compliance with such terms and conditions; (C) promptly provide to Adamas written

evidence of compliance with the obligation set forth in subsection (A) above; and (D) cooperate with Adamas regarding the enforcement of such terms and conditions. Any purported assignment in violation of this Section 12.7 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Notwithstanding the foregoing, Adamas shall have the right to, without Forest's consent, assign, sell, pledge, contribute or otherwise transfer to one or more Third Party(ies), in whole or in part, its rights to receive any of the payments under this Agreement, together with the right to receive reports pertaining to such payments and other information relating to the calculation of such payments, including any audit reports; provided, however, that if [*], Adamas shall [*].

12.8 Counterparts; Exchange by Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and that together shall constitute one and the same instrument. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by this Agreement notwithstanding that original copies of this Agreement may not be exchanged immediately. The Parties shall cooperate after execution of this Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.

12.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to a natural disaster, explosion, fire, flood, tornadoes, thunderstorms, earthquake, war, terrorism, riots, embargo, losses or shortages of power, labor stoppage, substance or material shortages, damage to or loss of product in transit not due to a failure by such Party or its Affiliates to exercise reasonable care, events caused by reason of Laws of any Governmental Authority, events caused by acts or omissions of a Third Party not induced or solicited by such Party or its Affiliates, or any other cause reasonably beyond the control of such Party or its Affiliates.

12.10 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party except for ARTICLE X with respect to an Indemnified Party. No such Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

12.11 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other, except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said other Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the

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contrary, the legal relationship under this Agreement of each Party to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties. For purposes of this Agreement, except as expressly provided otherwise, in no event shall the conduct of activities hereunder (a) by Adamas or any of its Affiliates be deemed to be "on behalf of" Forest or its Affiliates or (b) by Forest or any of its Affiliates be deemed to be "on behalf of" Adamas or its Affiliates.

12.12 Performance by Affiliates. Each Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

12.13 Further Assurance. Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to implement or give effect to this Agreement.

{Signature page follows}

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IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

FOREST LABORATORIES HOLDINGS LIMITED

ADAMAS PHARMACEUTICALS, INC.

By: /s/ David Solomon

By: /s/ Gregory T. Went

Name: David Solomon

Name: Gregory T. Went

Title: Assistant Secretary

Title: CEO

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Schedule 1.6**Certain Adamas Know How(1)****Document**

[*]

Document Name

[*]

(1) Note: The documents set forth in this Schedule 1.6 and the data contained therein constitute Adamas Know-How to the extent they are proprietary or non-public and otherwise satisfy the definition of Know-How.

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Schedule 1.7**Adamas Memantine Patent Rights****Case**

[*]

Application No.

[*]

Patent No.

[*]

Status

[*]

Country

[*]

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Schedule 1.9**Adamas Product Trademark Rights**

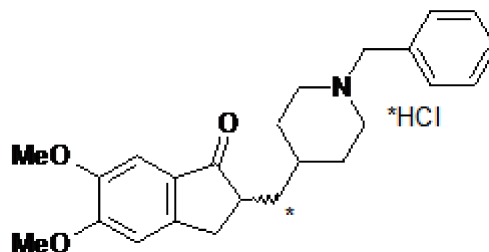
ARIMENDA™

<http://www.arimenda.com><http://www.arimenda.net><http://www.arimenda.org>

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Schedule 1.31**Donepezil**



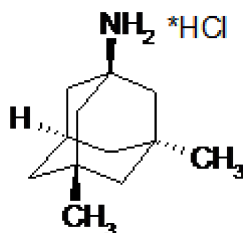
Donepezil hydrochloride

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Schedule 1.59

Memantine



Memantine hydrochloride

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Schedule 1.80

Regulatory Plan

[*]

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Schedule 2.6

Transferable Contracts

- [*]

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Schedule 6.8

Adamas Wiring Instructions

DOMESTIC WIRE TRANSFER:

TO: [*]
 ROUTING #: [*]
 FOR CREDIT OF: Adamas Pharmaceuticals, Inc.
 CREDIT ACCOUNT #: [*]
 BY ORDER OF: [Name of Sender]

INTERNATIONAL WIRE TRANSFER:

TO: [*]
 ROUTING #: [*]
 SWIFT CODE: SVBKUS6S
 FOR CREDIT OF: Adamas Pharmaceuticals, Inc.
 CREDIT ACCOUNT #: [*]
 BY ORDER OF: [Name of Sender]

Forest Wiring Instructions

[*]

IBAN: [*]

SWIFT: [*]

Intermediary SWIFT: [*]

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Schedule 7.3(h)

CREATE Act Subject Matter

To facilitate CREATE Act filings pursuant to Section 7.3(h), the Parties agree that each Party may include a reference to this Agreement in a patent application in order to exercise its rights under Section 7.3(h), which reference consists essentially of the following statement:

“The contents of this application are under a joint research agreement within the meaning of 35 U.S.C. § 103(c) and 37 C.F.R. § 1.104(c)(4)(ii) (or after March 16, 2013, 35 U.S.C. § 100(h) and § 102(c) and corresponding regulations) entered into by and between Forest Laboratories Holdings Limited and Adamas Pharmaceuticals, Inc. on November 13, 2012 (the ‘Joint Research Agreement’). The Joint Research Agreement was in effect on or before the date that the invention claimed in this application was made, and the invention claimed in this application was made as a result of activities undertaken within the scope of the Joint Research Agreement.”

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Schedule 8.5

Form of Joint Press Release

Forest Laboratories and Adamas Pharmaceuticals Enter into Licensing Agreement for the Development and Commercialization of a Fixed Dosed Combination of Namenda XR® and Donepezil for Alzheimer's Disease

NEW YORK & EMERYVILLE, CA — Forest Laboratories, Inc. (NYSE: FRX), an international pharmaceutical company, and Adamas Pharmaceuticals, Inc. announced today that they have entered into an agreement for the development and commercialization of a fixed dosed combination (FDC) of Namenda XR® (memantine HCl extended release) and donepezil HCl as a once daily therapy for the treatment of moderate to severe dementia of the Alzheimer's type in the United States. Under the agreement, Forest and Adamas will collaborate on the development of the FDC and Forest will have exclusive US commercialization rights. Forest is responsible for all development and commercialization activities. Namenda XR® is Forest's FDA approved, once daily formulation of its successful Alzheimer's therapy Namenda®. Based on a development plan agreed to by Adamas and the FDA, the FDC is expected to launch in 2015 following FDA approval. The product will be covered by multiple Adamas patents that extend to 2029. Forest sells Namenda in the US under a 2000 license from Merz + Co. GmbH & Co.

Pursuant to the agreement, Forest will pay Adamas \$65 million upfront and up to \$95 million in future development and FDA approval milestones. Adamas will receive royalties on US net sales beginning 5 years after launch for FDC products and any additional memantine products for which Adamas' patents are listed in the FDA's Orange Book.

"We are pleased to enter into this partnership with Adamas, which will enable us to enhance our life cycle program for Namenda," said Howard Solomon, Chairman, Chief Executive Officer and President of Forest. "Adamas has made impressive progress with its combination extended release memantine and donepezil program. Forest is the ideal company to complete the development of this product and commercialize it in the US, in light of our successful track record in the field of Alzheimer's disease with Namenda. Over 60% of Namenda patients already take Namenda together with an acetylcholinesterase inhibitor like donepezil, which creates a substantial market opportunity for this fixed dose combination product. Namenda and donepezil work in different ways and studies support that when used together they improve cognition, function, and behavior in some patients with moderate to severe Alzheimer's disease. This new fixed combination, which reduces the pill requirement from three tablets to one and the dosing frequency from two times per day to once per day, can benefit physicians, caregivers, and patients."

Gregory T. Went, Chief Executive Officer of Adamas Pharmaceuticals said: "We are pleased to partner with Forest, the market leader in Alzheimer's products, to bring our fixed dose combination of extended release memantine and donepezil — the first such combination therapy for Alzheimer's disease — to the US market. This collaboration will accelerate this innovative product's development towards a 2014 US NDA filing, and allow Adamas to focus our attention

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on the ex-US market for the product and to continue the ongoing development of Nurelin™, our late-stage product candidate for the treatment of CNS disorders, including Parkinson's disease."

About Adamas Pharmaceuticals

Adamas Pharmaceuticals, based in Emeryville, California with operations in Bangalore, India, is the leading developer of aminoadamantane-based therapeutics for CNS disorders. The company's research and development platform is focused on developing controlled release versions and optimized fixed dose combinations of aminoadamantanes to address major dosing and titration challenges that limit the use of currently available therapeutics. Adamas is advancing two programs from this platform. Nurelin (amantadine HCl extended release capsules) is currently in Phase 3 clinical studies, initially for levodopa-induced dyskinesia in patients with Parkinson's disease. A registration program is also underway for the fixed dose combination of memantine HCl extended

release and donepezil HCl for Alzheimer's disease. Both products are designed to improve tolerability and clinical efficacy, and to provide superior clinical and health economic benefits. For more information about Adamas, please visit www.adamaspharma.com.

About Forest Laboratories

Forest Laboratories' (NYSE: FRX) longstanding global partnerships and track record developing and marketing pharmaceutical products in the United States have yielded its well-established central nervous system and cardiovascular franchises and innovations in anti-infective, respiratory, gastrointestinal, and pain management medicine. Forest's pipeline, the most robust in its history, includes product candidates in all stages of development across a wide range of therapeutic areas. Forest is headquartered in New York, NY. To learn more, visit www.FRX.com.

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories' Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings. Forest assumes no obligation to update forward looking statements contained in this release to reflect new information or future events or developments.

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Schedule 9.1

Adamas Schedule of Exceptions

This Schedule of Exceptions and the information and disclosures contained herein are intended only to qualify and limit the representations, warranties and covenants of Adamas contained in the Agreement, and shall not be deemed to expand in any way the scope or effect of any of such representations, warranties or covenants. The section numbers in this Schedule correspond to the section numbers in the Agreement. The headings used in this Schedule are for reference only and shall not be considered when interpreting the scope of disclosure. Disclosure of any information or document herein is not a statement or admission that it is material or required to be disclosed herein. Nothing in this Schedule of Exceptions constitutes an admission of any liability or obligation of Adamas to any third party, or an admission to any third party against the interests of Adamas. No disclosure in this Schedule of Exceptions relating to any possible breach or violation of any agreement, law or regulation shall be construed as an admission or indication to any third party that any such breach or violation exists or has actually occurred. References to any document do not purport to be complete and are qualified in their entirety by the document itself. Capitalized terms used but not defined herein shall have the same meanings given them in the Agreement.

[*]

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Schedule 9.1(t)

Material Contracts

Reference is made to those Transferable Contracts set forth in Schedule 2.6.

Contracted Party	Document Description
[*]	[*]

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Schedule 9.2

Forest Schedule of Exceptions

[*]

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Schedule 9.2(e)

[*]

<6 pages omitted>

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Schedule 9.2(h)

[*]

<32 pages omitted>

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Schedule 11.6

Reversion of Certain FDC Products

In the event of termination of this Agreement with respect to the FDC Products, the following provisions shall apply upon the effective date of such termination of this Agreement (or such later date as applies pursuant to Section 11.6(c) of the Agreement) (“Termination Effective Date”):

(a) Regulatory Filings. Forest shall, and shall cause each of its Affiliates and Sublicensees to, promptly assign and transfer to Adamas all filings with Regulatory Authorities in the Territory, including copies of all correspondence, written minutes of meetings and memoranda of conversations with such Regulatory Authorities, and all Regulatory Approvals in the Territory, in each case made or obtained in connection with the Development, Manufacture, and Commercialization of FDC Products that are then being Developed or Commercialized by Forest or its Affiliates or Sublicensees [*] or, if no FDC Products are then being Developed or Commercialized by Forest or its Affiliates or Sublicensees, the FDC Product most recently Developed or Commercialized by Forest or its Affiliates or Sublicensees (such products, as well as any improvements or modifications made by Adamas thereafter, the “Reverted FDC Products”) (including INDs and NDAs), in each case, that are Controlled by or under the authority of Forest or its Affiliates as of the Termination Effective Date and pertain solely to the Reverted FDC Products (“Reverted FDC Product Regulatory Filings”), and for clarity such transfer of rights under the Reverted FDC Product Regulatory Filings shall include an irrevocable right to access and reference any filings referenced in such Reverted FDC Product Regulatory Filings (together with [*] to the extent related to the Reverted FDC Products). Forest shall, and shall cause its Affiliates and Sublicensees to, take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such Reverted FDC Product Regulatory Filings to Adamas. Forest shall also promptly transfer all safety information and data with respect to the Reverted FDC Products as they exist as of the Termination Effective Date that are Controlled by or under the authority of Forest or its Affiliates as of Termination Effective Date. If applicable Law prevents or delays the assignment of any such Reverted FDC Product Regulatory Filings to Adamas, Forest shall grant (and shall cause each of its Affiliates and Sublicensees to grant), and does hereby grant, to Adamas an exclusive and irrevocable right of access and reference to such Reverted FDC Product Regulatory Filings (including any filings referenced in such Reverted FDC Product Regulatory Filings, together with [*] to the extent related to the Reverted FDC Product) for the purpose of Developing and Commercializing Reverted FDC Products in the Territory, and shall cooperate fully to make such benefits of such Reverted FDC Product Regulatory Filings available to Adamas or its designee(s). In each case, unless otherwise required by any applicable Law, the foregoing assignment and transfer shall be made within [*] after the Termination Effective Date, including providing to Adamas copies of all such Reverted FDC Product Regulatory Filings. The activities under this Paragraph (a) shall [*]. Adamas acknowledges that, unless and until the execution of a Sublicense Agreement (as defined below), Forest shall have no obligation under this Paragraph (a) with respect to any information or other intellectual property [*] and all rights under this Paragraph (a) are subject to [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

(b) Licenses.

(i) Termination and Grant of Licenses.

(A) All rights and licenses granted to Forest under Article 2 shall terminate solely with respect to the FDC Products, but shall remain in effect with respect to the Reverted FDC Products to the extent and for so long as necessary to allow Forest to perform its obligations under this Schedule 11.6. Forest shall return to Adamas all Confidential Information of Adamas related solely to the FDC Products within [*] after the Termination Effective Date.

(B) Forest, on behalf of itself and its Affiliates, agrees to grant to Adamas, effective upon the Termination Effective Date, an exclusive (subject to any (sub)licenses granted by Forest consistent with this Agreement as of the Termination Effective Date), irrevocable ([*] or the [*]), perpetual right and license, with the right to grant and authorize sublicenses, in the Territory under (1) the Forest Know-How and Forest Patent Rights and (2) all other Patent Rights and Know-How Controlled by Forest or its Affiliates ([*], which is [*]) (provided that such exclusivity shall be limited to the extent that any of such rights [*] for so long as [*]), in each case of (1) and (2), that are necessary to Develop, Manufacture and Commercialize the Reverted FDC Products as they exist as of the Termination Effective Date in the Territory (the “Forest Reversion Intellectual Property”) solely for use to Develop, Manufacture and Commercialize the Reverted FDC Products in the Territory in accordance with this Schedule 11.6 and the surviving terms of the Agreement. Such license shall be royalty-free and fully paid except as provided in Section 2.1(d), the terms of which such Section 2.1(d) shall apply to Forest with respect to the Forest Reversion Intellectual Property as if it were Adamas and to Adamas as if it were Forest, *mutatis mutandis*. In the event that [*], such license shall be granted pursuant to the Sublicense Agreement (as defined in Paragraph (b)(i)(C)). The Parties’ rights and obligations with respect to the prosecution, maintenance and enforcement of the Forest Reversion Intellectual Property, including any Patent Rights and Know-How that may be [*], shall [*] Article 7 of the Agreement with respect to the Forest Reversion Intellectual Property.

(C) Adamas acknowledges that the Development and Commercialization in the Territory of the Reverted FDC Product [*] and that the license described in Paragraph (b)(i)(B) [*], and Forest shall [*] to Adamas, [*] and [*],

provided that, if, [*], [*] without [*], then [*]. If [*], the Parties shall [*] to the terms of [*], including any obligation of [*], in each case as such terms exist as of the Termination Effective Date (any such agreement, the “Sublicense Agreement”).

(ii) Adamas Memantine Patent Rights.

(A) If [*] the Agreement, [*] and [*] (1) the Adamas Memantine Patent Rights that solely relate to the FDC Products (the “Adamas FDC Patent Rights”) and (2) unless [*], the Adamas Product Trademark Rights, in each case ((1) and (2)) that [*] the Agreement, and shall [*] in order to [*] and [*] and [*] pursuant to this clause (b)(ii)(A), including [*]. Further, in the case of any such termination, [*], on behalf of itself and its Affiliates, [*], effective upon the Termination Effective Date, [*] and [*] and [*] any Adamas Memantine

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Patent Rights [*] (the “Adamas FDC and ER Patent Rights”) [*] (but for clarity, [*] such patents with respect to any Products other than FDC Products).

(B) The Adamas FDC Patent Rights shall for purposes of this Agreement be [*]. Adamas shall have the sole right to enforce the Adamas FDC Patent Rights with respect to an infringement by FDC Products under Section [*] of the Agreement, subject to any other applicable terms of this Agreement, including the [*] provisions of Sections [*]. For purposes of clarity, the Parties agree that the Adamas FDC Patent Rights existing as of the Effective Date are as follows: [*].

(C) Without limiting the Parties’ obligations under Section 7.3, with regard to any Adamas FDC and ER Patent Rights, the Party that has the right to prosecute or maintain such Patent Rights shall notify the other Party in advance of any prosecution or maintenance action with respect to such Patent Rights that would be reasonably expected to have a material adverse effect on the other Party’s Products in the Territory. Notwithstanding Section [*], [*] shall [*] any Adamas FDC and ER Patent Right in the Territory with respect to the FDC Products under Section [*], with [*] and [*], in each case subject to [*]. If [*], (A) any such [*] shall [*] with respect to the other Adamas FDC and ER Patent Rights (including with respect to a [*] Adamas FDC and ER Patent Right); and (B) [*] shall (1) keep [*] reasonably informed of the status of [*] activities that pertain to such Adamas FDC and ER Patent Right, and (2) [*] reasonable proposals or comments as part of such [*].

(c) Trademark Rights. If the Termination Effective Date occurs *after* the launch of the Reverted FDC Product(s) in the Territory, then, subject to any required consents of [*], Forest agrees to grant to Adamas [*] an exclusive, irrevocable, perpetual right and (sub)license, with the right to grant and authorize sublicenses, in the Territory in and to (i) any Trademarks Rights under which the Reverted FDC Products were being Commercialized in the Territory as of the Termination Effective Date ([*], if applicable), and (ii) all Internet domain names containing only such Trademark Right and no other Trademark Rights as its URL address or any part of such address, in each case ((i) and (ii)) Controlled by Forest or its Affiliates, subject to customary trademark conditions, including the trademark conditions set forth in [*]. Such license shall be royalty-free and fully paid except that Adamas shall be responsible for any payment owed to any Third Party by Forest that arises from the use of the Trademark Rights licensed to Adamas under this Paragraph (c). It is understood that the license set forth in this Paragraph (c) do not include the name of Forest or any of its Affiliates or any Third Party, nor the corporate logo, service mark, or trademark for Forest or for any of its Affiliates or any Third Party as a corporate entity, nor any Trademark Rights used in connection with any Products other than the Reverted FDC Products.

(d) Data and Know-How. Forest shall, at the request of Adamas, provide Adamas access to, and/or copies of, all Know-How in its or its Affiliates’ possession and Control pertaining to any Reverted FDC Product, or the Manufacture or use thereof, to the extent actually used in connection with a Reverted FDC Product during the Term, in each case as necessary for Adamas to Develop, Manufacture and Commercialize the Reverted FDC Products as of the date of such termination (including all Know-How pertaining to the Manufacture of the Reverted FDC Product(s) as so used (including active pharmaceutical ingredients or other raw materials or

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work-in-process related thereto)), to the extent such Know-How has not been provided previously to Adamas under this Agreement, except that any disclosures of Know-How [*] shall be made solely pursuant to the Sublicense Agreement.

(e) Development; Clinical Trials. Subject to the provisions set forth below relating to safety risks, the following shall apply. Adamas may, at its election, assume the conduct of any or all Development activities set forth under the then-current Development Plan for the Reverted FDC Products [*]. In addition, if any clinical trial (including any Phase IV Clinical Trial) has been initiated (i.e., first patient dosed) and is being conducted as of the Termination Effective Date for a Reverted FDC Product (each, an “On-Going Clinical Study”) by or under authority of Forest or its Affiliate, Forest agrees, as Adamas may request, to (i) promptly transition to Adamas or its designee some or all of such On-Going Clinical Studies (including all results and data generated therefrom) and the activities related to or supporting such trials, (ii) continue to conduct such On-Going Clinical Studies and provide to Adamas any and all results and data generated therefrom for a period requested by Adamas [*], or (iii) terminate such On-Going Clinical Studies in a manner consistent with applicable Laws; provided, however, that in the event that Forest reasonably determines that an On-Going Clinical Study being run by Forest or its Affiliate would pose an unacceptable safety risk for subjects participating in such On-Going Clinical Study, then Forest shall not be obligated to continue such On-Going Clinical Study or to transfer control of such On-Going Clinical Study to Adamas, and Forest shall provide Adamas with a full explanation of Forest’s safety issue concern and, if requested by Adamas, reasonable documentation thereof and such additional information in the Control of Forest or its Affiliates as of the Termination Effective Date (i.e., Forest shall not be required to generate or collect any new data) as may be necessary to permit Adamas to fully understand and assess the safety issue raised by Forest. Forest shall be responsible for all of its own costs and expenses associated with Forest’s activities under this Paragraph (e) for a period of [*] after the Termination Effective Date and Adamas shall be responsible for all of its own costs and expenses (including all out-of-pocket costs and FTE Costs) associated with Adamas’ activities under this Paragraph (e) and for all of Forest’s costs and expenses after the specified [*] period.

(f) Supply. If Forest or its Affiliate is Manufacturing, itself or through a Third Party, any Reverted FDC Product(s) (including any active pharmaceutical ingredient(s) related thereto) as of the Termination Effective Date, then Forest (or its Affiliate) shall, or shall use Commercially Reasonable Efforts to cause such Third Party to, at Adamas’ request, continue to provide such Reverted FDC Product(s) (and/or any active pharmaceutical ingredient(s) included therein solely for use in Manufacturing such Reverted FDC Product(s)) for sale in the Territory to Adamas, at a price equal to (i) in the case of supply by Forest or its Affiliate, [*] or (ii) in the case of supply by such Third Party, [*], in each case ((i) and (ii) from the Termination Effective Date until such time as Adamas is able to secure an acceptable alternative manufacturing source from which sufficient quantities of such Reverted FDC Product may be procured, but in any event [*] after the Termination Effective Date (or for a longer period if agreed upon by the Parties in writing); provided that Adamas shall use Commercially Reasonable Efforts to secure an acceptable alternative manufacturing source for the Reverted FDC Product(s) as promptly as practicable; provided further that the provisions of this Paragraph

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(f) shall be subject to [*] and [*] arising from the sale of such Reverted FDC Product(s) pursuant to this Paragraph (f) or any subsequent sale of such Reverted FDC Product(s) by Adamas.

(g) Commercialization Wind-Down. To avoid disruption of supply of any Reverted FDC Product(s) to patients if this Agreement is terminated after the launch of such Reverted FDC Product(s) in the Territory, subject to the last sentence of this Paragraph (g), Forest and its Affiliates and Sublicensees shall continue to use Commercially Reasonable Efforts to distribute and sell such Reverted FDC Product(s) in the Territory, in accordance with the terms and conditions of this Agreement, until the date on which Adamas notifies Forest that Adamas has arranged for an alternate method for distributing the Reverted FDC Product(s) in the Territory, but [*] from the Termination Effective Date (the “Wind-Down Period”), provided that Adamas may terminate such activities upon [*] notice to Forest; provided further that Adamas shall use Commercially Reasonable Efforts to secure such alternate arrangements as promptly as practicable. If Adamas requests that Forest and its Affiliates and Sublicensees distribute and sell such Reverted FDC Product(s) during the Wind-Down Period, Adamas shall grant, and hereby grants, to Forest for the duration of the Wind-Down Period, a non-exclusive license under any and all applicable Patent Rights and Trademark Rights Controlled by Adamas or its Affiliates to use, sell, offer to sell, have sold, import and otherwise Commercialize such Reverted FDC Product(s) in the Field in the Territory, solely to perform such distribution and sale with respect to such Reverted FDC Product(s) as requested by Adamas during the Wind-Down Period. For the avoidance of doubt, during the Wind-Down Period, Adamas shall have the right to engage one or more other partner(s) or distributor(s) for Reverted FDC Products in the Territory during the Wind-Down Period. Any Reverted FDC Products sold or disposed by Forest or its Affiliates or Sublicensees during the Wind-Down Period shall constitute Net Sales of FDC Products

and shall be subject to any applicable payment obligations under Article VI. Within [*] following the expiration of the Wind-Down Period, Forest shall notify Adamas of any quantities of such Reverted FDC Product(s) (including any active pharmaceutical ingredients or other raw materials or work-in-process inventory specifically allocated by Forest or its Affiliates or Sublicensees to the Manufacture of such Reverted FDC Product(s)) remaining in Forest's or its Affiliate's or Sublicensee's inventory for the Territory, and Adamas shall purchase such quantities of such Reverted FDC Product(s) and such raw materials or work-in-process inventory from Forest at a price equal to [*]. Upon receipt of payment therefor, Forest shall promptly transfer to Adamas such quantities of inventory. Notwithstanding anything in this Paragraph (g), Forest may immediately cease Commercialization of any Reverted FDC Product in the Territory for a safety reason at any time.

(h) Agreements. Upon Adamas' request, any agreement to which Forest or its Affiliate or Sublicensee is a party and which relates solely to one or more Reverted FDC Product(s) in the form existing as of the Termination Effective Date shall (subject to obtaining any Third Party's consent to such assignment) be assigned to Adamas, and if not so assigned, the Parties shall coordinate to ensure that Adamas obtains the benefits under such contracts as reasonably necessary to exercise its rights and licenses hereunder until Adamas is able to execute a written agreement directly with the other party to such agreement providing such benefits or a comparable alternate arrangement, but in no event more than [*] from the Termination Effective Date; provided that Adamas shall use Commercially Reasonable Efforts to execute a written agreement directly with the other party to such agreement during such [*] period. Forest shall

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use Commercially Reasonable Efforts to assist Adamas in negotiating and executing such an agreement with such counterparty. Without limiting the foregoing, Forest's (and any of its Affiliates') sublicenses to Third Parties with respect to the Reverted FDC Products shall be assigned to Adamas to the extent possible under the terms of the applicable sublicense and to the extent that the applicable sublicense solely relates to the Reverted FDC Products, subject to such Sublicensee's prior written consent (in which case, such Sublicensee shall be exempt from the other provisions of this Schedule 11.2(e)).

(i) Transition. With respect to matters not already covered above in Paragraphs (a) through (h), the Parties agree, and agree on behalf of their Affiliates, at each Party's expense, to reasonably cooperate with each other (and their designees) as necessary to facilitate a smooth, orderly and prompt transition of the ongoing Development, Manufacturing and Commercialization of the Reverted FDC Products in the Territory within [*] of the Termination Effective Date.

(j) Additional Matters. Upon the Termination Effective Date, the Parties' rights and obligations under this Agreement shall terminate with respect to the FDC Products (including any license granted to Forest hereunder with respect to such FDC Products), except that (A) those provisions expressly set forth in this ARTICLE XI as surviving such termination shall survive; and (B) the following provisions shall survive with respect to the FDC Products (until expiration of this Agreement, after which such provisions shall survive solely as set forth in Section 11.7): [*]. In addition, [*] survives as set forth therein, including for clarity with regard to Development of FDC Products by Adamas, its Affiliates and (sub)licensees for the Territory if [*] or [*], and [*] survives as set forth therein, [*] or [*] with regard to the FDC Products [*] or [*]. Finally, for clarity, Adamas' obligations in Section [*] shall apply with respect to the Adamas FDC Patent Rights. Subject to the foregoing, all provisions of this Agreement with respect to Products other than FDC Products shall, for clarity, survive such a termination and in no event shall such a termination be construed to modify or limit any rights or obligations of a Party with respect to any Product other than an FDC Product.

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EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

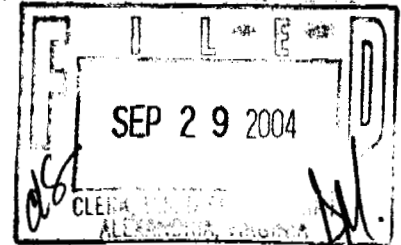
UNITED STATES OF AMERICA,
ex rel. PROMEGA CORPORATION,
et al.,

Plaintiffs,

v.

HOFFMAN-LA ROCHE INC., et
al.,

Defendants.



Civil Action No. 03-1447-A

ORDER

This matter comes before the Court on Motions to Dismiss the Amended Complaint filed by Defendants Hoffman-LaRoche Inc. and Roche Molecular Systems, Inc. as well as by Defendants PE Corporation, PE Biosystems Group, the Perkin-Elmer Corporation, and PE Applied Biosystems.

For the reasons stated in the accompanying memorandum opinion, it is hereby

ORDERED that all Defendants' Motions to Dismiss are GRANTED and the case is DISMISSED with PREJUDICE.

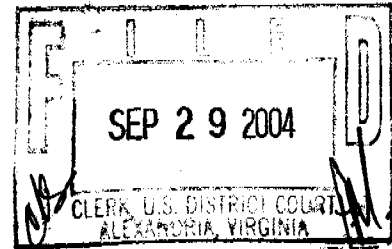
A handwritten signature or set of initials, possibly "M", enclosed in a circular scribble.

Claude M. Hilton
CHIEF UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
September 29, 2004

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division



UNITED STATES OF AMERICA,
ex rel. PROMEGA CORPORATION,
et al.,

Plaintiffs,

v.

Civil Action No. 03-1447-A

HOFFMAN-LA ROCHE INC., et
al.,

Defendants.

MEMORANDUM OPINION

This matter comes before the Court on Motions to Dismiss the Amended Complaint filed by Defendants Hoffman-LaRoche Inc. and Roche Molecular Systems, Inc. as well as by Defendants PE Corporation, PE Biosystems Group, the Perkin-Elmer Corporation, and PE Applied Biosystems. Defendants assert that Plaintiffs' claims should be dismissed under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction and under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted.

Plaintiffs filed the instant case on April 23, 2000 alleging violations of the False Claims Act, pursuant to 31 U.S.C. § 3729 (2003). This Court dismissed Plaintiffs' Complaint without

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prejudice pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim with sufficient particularity as required by Federal Rule of Civil Procedure 9(b). On July 13, 2004, Plaintiffs filed an Amended Complaint alleging that Defendants violated the False Claims Act on nine counts.

In Counts I through III of the Amended Complaint, Plaintiffs allege that "every claim, invoice, demand, solicitation, representation, relationship, contract or transaction" sent to the United States Government or government-funded entities for payment by the Defendants was a false or fraudulent claim in violation of section 3729(a)(1) of the False Claims Act because Defendants based all of these claims on "fraudulently obtained" patents. Am. Compl. ¶¶ 260-283. In Counts IV through VI, Plaintiffs allege that Defendants used false records or statements to get the United States Government or government-funded entities to pay false or fraudulent claims, in violation of section 3729(a)(2) of the False Claims Act.

Count VII alleges a conspiracy between the Defendants to fraudulently obtain patents for Taq and then submit false claims for payment to the United States Government based on those patents, in violation of section 3729(a)(3) of the False Claims Act. In Count VIII, Plaintiffs allege that Defendants used false

statements or records to conceal or avoid repayment of monies to the United States Government in violation of section 3729(a)(7) of the False Claims Act. Finally, in Count IX, Plaintiffs allege that Defendants wrongfully retained monies properly owed to the United States, in violation of section 3729(a)(4) of the False Claims Act. Plaintiffs seek \$128 million dollars in damages and ask the Court to treble those damages.

When ruling on a motion to dismiss, this Court must "assume the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations." Eastern Shore Markets, Inc. v. J.D. Assocs. Ltd. P'ship, 213 F.3d 175, 180 (4th Cir. 2000). While the Court must consider the facts in the light most favorable to the plaintiff, unreasonable conclusions without factual support, unwarranted inferences, and arguments are insufficient to state a claim upon which relief can be granted. Id.

Defendants move to dismiss under 12(b)(6) for failure to state a claim with the sufficient particularity required under Rule 9(b) of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 9(b) (2004). Claims brought under the False Claims Act are charges of fraud and are subject to Rule 9(b) under which plaintiffs must plead their complaint with particularity.

Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783-84 (4th Cir. 1999); See Fed. R. Civ. P. 9(b) (2004). A Complaint's "lack of compliance with 9(b)'s pleading requirements is treated as a failure to state a claim under 12(b)(6)." Harrison, 176 F.3d at 783 n. 5. Particularity in pleading refers to "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." Id. at 784 (citing 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure: Civil § 1297, at 590 (2d ed. 1990)). In other words, the Complaint must state the "who, what, when, where, and how" of the fraud to plead it with sufficient particularity. United States ex rel. Detrick v. Daniel F. Young, Inc., 909 F. Supp. 1010, 1022 (E.D. Va. 1995).

Plaintiffs' Amended Complaint expands their three original counts into nine counts and adds over seventy pages of details to their original Complaint. Despite all of these additions, Plaintiffs have failed to plead the essential elements and details with sufficient particularity to withstand 9(b) scrutiny. Just as in the original Complaint, Plaintiffs continue to outline vague, broad schemes.

In Counts I through VI, Plaintiffs fail to describe what was obtained through the alleged fraud. Instead, the Amended

Complaint repeats the same vague allegations of higher prices, see, e.g., Am. Compl. ¶ 168, and generalized platitudes regarding the "reduced overall competition in the Tag market," see, e.g., Am. Compl. ¶¶ 180-82.

Furthermore, Counts I through VI fail to specify when and where the false claims were made. The invoices themselves were not fraudulent, because they contained the exact terms agreed to by the Government. Instead, Plaintiffs allege that Defendants' predecessors made misrepresentations to the USPTO in order to obtain certain patents, and that years later Defendants used those patents to obtain contracts with the Government. Under Plaintiffs' theory, every invoice submitted for payment under these contracts violated the False Claims Act because of the misrepresentations to the USPTO from years ago. This theory is fatally flawed because there is a disconnect between the alleged misrepresentations to the USPTO and the invoices submitted to the Government, and Plaintiffs fail to draw a meaningful connection between the two.

Plaintiffs attempt to resolve this disconnect by claiming that the misrepresentations somehow induced the Government to enter into contracts with the Defendants. Plaintiffs have failed, however, to allege any facts that support such a theory.

Paragraph 136, for example, alleges that "[o]n information and belief, employees, independent contractors, agents or representatives of Defendants . . . discussed the obligation to pay certain prices for Taq and related products/processes." This paragraph, however, fails to explain who these agents were, what they said, to whom, in what context and capacity, about what products; therefore, it is too vague to satisfy the 9(b) requirement.

Count VII alleges a conspiracy dating all the way back to a meeting on December 18, 1988. The Amended Complaint does not identify the role that each Defendant played in the conspiracy and more importantly, it fails to identify Defendants' culpable conduct. The Amended Complaint refers merely to "conspiracy meetings" in which the Defendants discussed "marketing plans," "pricing and royalty rates" and "Taq sales." Am. Compl. ¶ 101. It appears to the Court that Plaintiffs are merely alleging facially legal conduct and labeling it a "conspiracy." This sort of fishing expedition is exemplary of the conduct that Federal Rule of Civil Procedure 9(b) seeks to prevent.

Finally, Plaintiffs have failed to sufficiently plead the statutory elements required under 31 U.S.C. §§ 3729(a)(4) & (7) and accordingly Counts VIII and IX should be dismissed. Under §

3729(a)(7), Plaintiffs must show that Defendants "knowingly [made] . . . a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7). While Plaintiffs allege that this "obligation" accrued as a result of Defendants' failure to observe certain unidentified "fiduciary and contractual" duties owed to the Government, neither the duties nor any wrongfully obtained monies are identified. Nor do Plaintiffs identify what false statement was made by whom at the time a legal duty to pay the Government arose. Accordingly, Count VIII should be dismissed.

Similarly, § 3729(a)(4) imposes liability if a Defendant "has possession, custody, or control of property or money used . . . by the Government and, intending to defraud the Government or willfully to conceal the property, delivers . . . less property than the amount for which the person receives a certificate or receipt." 31 U.S.C. § 3729(a)(4). The Amended Complaint alleges that Defendants concealed an overpayment by the Government, but fails to allege the delivery of property to the United States in return for a receipt. Since Plaintiffs have failed to plead all of the essential elements of § 3729(a)(4), Count IX should be dismissed.

Even if the court found that Plaintiffs did state a claim for relief, the Amended Complaint should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1) because the court lacks subject matter jurisdiction to hear the case. Under the False Claims Act, there is a two step inquiry to determine whether a court has subject matter jurisdiction. First, the court must determine whether the action is "based upon the public disclosure of allegations or transactions." If the action is based upon public disclosure, the court must then determine whether the plaintiff qualifies as an "original source." 31 U.S.C. § 3730(e)(4)(A) (2003).

In the first inquiry, the term "based upon" means derived from, such that the action is based upon public disclosure only where the plaintiff has actually derived from that disclosure knowledge of facts underlying the action. United States ex rel Siller v. Becton Dickinson & Co. by & Through Its Microbiology Sys. Dev., 21 F.3d 1339, 1348 (4th Cir. 1994). The present action is, in fact, derived from public information. Plaintiffs base their complaint on information from administrative and civil proceedings, litigation before the United States District Court for the Northern District of California, discovery in this very case, the news media, marketplace activities and public

statements. The publicly filed patents themselves provided the basis for Plaintiff's information leading to claims of fraudulent patent applications. Dimond Dep. ¶¶ 17:11-17:20, 20:23-21:2; 2d Dimond Aff. ¶¶ 13-14. All of Plaintiffs' "independent study and analysis" was derived from those public filings. Furthermore, Plaintiffs rely heavily on information obtained from Hoffmann-La Roche, Inc. et al. v. Promega Corp., 1999 U.S. Dist. LEXIS 19059 (N.D. Cal. 1999). Am. Compl. ¶ 46. In fact, practically all of Plaintiffs' allegations regarding the alleged fraudulent claims and the alleged conspiracy comes directly from public information. Am. Compl. ¶ 62.

Once it is established that the Plaintiffs based their claim upon public information, the second inquiry to determine subject matter jurisdiction asks whether the Plaintiffs qualify as an "original source" of the public information. A party is an original source if they have "direct and independent knowledge of the information on which the allegations are based and [have] voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B) (2002). According to the Fourth Circuit, a relator has direct knowledge "if he acquired it through his own efforts, without an intervening agency." Grayson v. Advanced Management Technology,

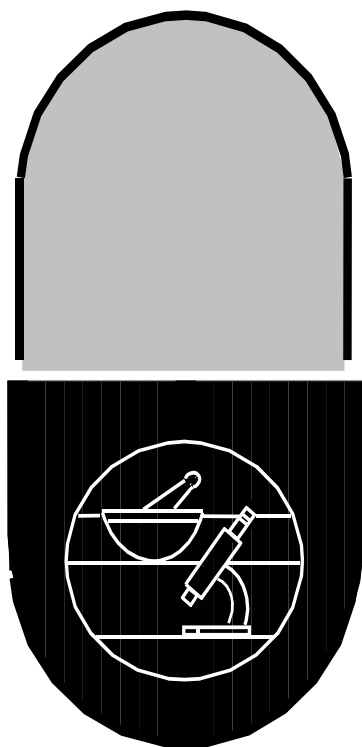
Inc., 221 F.3d 580, 583 (4th Cir. 2000). A relator has independent knowledge "if the knowledge is not dependent on a public disclosure." Id. In the present case, Plaintiffs depend heavily on the litigation in the California District Court and on other public disclosures. Plaintiffs' knowledge is neither direct nor independent. The Plaintiffs are not an original source as defined under the False Claims Act.

An appropriate Order shall issue.

Claude M. Hilton
CHIEF UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
September 29, 2004

EXHIBIT 9



APPROVED DRUG PRODUCTS

WITH

**THERAPEUTIC
EQUIVALENCE
EVALUATIONS**

37th EDITION

**THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER
SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY**

2017

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2016.

37th EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2017

2.2 DRUG PRODUCT ILLUSTRATION

SINGLE INGREDIENT

ACTIVE INGREDIENT	MEPERIDINE HYDROCHLORIDE
DOSAGE FORM; ROUTE OF ADMINISTRATION	INJECTABLE; INJECTION
TRADE OR GENERIC NAMES	HEXANON
REFERENCE LISTED DRUG* (+)	AP +! PAGE PHARMA 25MG/ML N013111 001 AUG 22, 1983
REFERENCE STANDARD * (!)	AP +! 50MG/ML N013111 002 AUG 22, 1983
	AP +! 75MG/ML N013111 003 AUG 22, 1983
	AP +! 100MG/ML N013111 004 JAN 04, 1989
	MEPERIDINE HCL
THERAPEUTIC EQUIVALENCE (TE)	AP GREENBERG PHARM 25MG/ML A064890 001 FEB 29, 1987
CODE FOR MULTISOURCE PRODUCT	AP 50MG/ML A064890 002 FEB 29, 1987
	AP 75MG/ML A064890 003 FEB 29, 1987
	AP 100MG/ML A064890 004 MAR 08, 1992
SINGLE SOURCE PRODUCT (NO TE CODE)	! TIMOKIM LLC 10MG/ML A099225 001 DEC 12, 1995
	AP JOHNSON MED 25MG/ML A099226 001 NOV 27, 1993
	! KENDRA PHARM 150MG/ML A079444 001 OCT 31, 1999
APPLICANT	
AVAILABLE STRENGTH(S) OF A PRODUCT	
APPLICATION NUMBER AND PRODUCT NUMBER	
PRODUCT NUMBER IS FOR FDA INTERNAL COMPUTER DATA USE ONLY	
APPROVAL DATE	

*NOTE: REFERENCE LISTED DRUG AND REFERENCE STANDARD ARE DISCUSSED IN THE PREFACE SECTION 1.4

MULTIPLE INGREDIENTS WITH PRODUCT INFORMATION

ALPHABETICALLY SORTED BY	
ACTIVE INGREDIENT	HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE
PRODUCT INFORMATION	TABLET; ORAL
	HYDROCHLOROTHIAZIDE, RESERPINE AND HYDRALAZINE HCL
	REINWALD LABS 25MG; 15MG; 0.1MG A069808 001 JAN 18, 1982

THIS EXAMPLE IS FOR PURPOSE OF ILLUSTRATION ONLY. IT DOES NOT REPRESENT ACTUAL PRODUCTS FROM THE PRESCRIPTION DRUG PRODUCT LIST.

2.3 THERAPEUTIC EQUIVALENCE EVALUATIONS ILLUSTRATION

DRUG PRODUCTS CODED **AB** (OR ANY CODE BEGINNING WITH AN "A") UNDER AN INGREDIENT AND DOSAGE FORM HEADING ARE CONSIDERED THERAPEUTICALLY EQUIVALENT ONLY TO OTHER PRODUCTS CODED **AB** (OR ANY CODE BEGINNING WITH AN "A") AND **NOT** TO THOSE CODED **BP** (OR ANY CODE BEGINNING WITH "B") AND ANY PRODUCTS NOT LISTED. DRUG PRODUCTS CODED **BP** (OR ANY CODE BEGINNING WITH A "B") ARE **NOT** CONSIDERED THERAPEUTICALLY EQUIVALENT TO ANY OTHER PRODUCT. FOR A COMPLETE EXPLANATION OF THE **TE** CODES REFER TO SECTION 1.7 OF THE *INTRODUCTION*.

SULFASALAZINE

TABLET; ORAL

FAZINE**AB** PARKLAND **500MG** **A042999** **001****SULAZINE****AB** URSA **500MG** **A042222** **001**SULFASALAZINE

BP BROWN 500MG A041297 001

SULFASALAZINE

TABLET; ORAL

FAZINE**AB** PARKLAND **500MG** **A042999** **001**SULFASALAZINE

BP BROWN 500MG A041297 001

SOUTH 500MG A067627 001

PRODUCTS CONSIDERED THERAPEUTICALLY
EQUIVALENT TO EACH OTHER

PRODUCTS CONSIDERED **NOT** THERAPEUTICALLY
EQUIVALENT TO ANY OTHER PRODUCTS LISTED

PRODUCTS CONSIDERED **NOT** THERAPEUTICALLY
EQUIVALENT TO EACH OTHER

NOTE: BOLD FONT AND UNDERLINING DENOTES MULTISOURCE PRODUCTS WHICH ARE CONSIDERED THERAPEUTICALLY EQUIVALENT.

THIS EXAMPLE IS FOR PURPOSES OF ILLUSTRATION ONLY. IT DOES NOT REPRESENT ACTUAL PRODUCTS FROM THE PRESCRIPTION DRUG PRODUCT LIST.

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PRESCRIPTION DRUG PRODUCT LIST

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DONEPEZIL HYDROCHLORIDE

TABLET; ORAL

DONEPEZIL HYDROCHLORIDE

<u>AB</u>		<u>10MG</u>	<u>A090686</u>	<u>002</u>	May 31, 2011
<u>AB</u>	TWI PHARMS INC	<u>23MG</u>	<u>A203104</u>	<u>001</u>	Oct 29, 2014
<u>AB</u>	UNICHEM LABS LTD	<u>5MG</u>	<u>A203656</u>	<u>001</u>	Jun 23, 2016
<u>AB</u>		<u>10MG</u>	<u>A203656</u>	<u>002</u>	Jun 23, 2016
<u>AB</u>	VIVIMED LABS	<u>5MG</u>	<u>A090551</u>	<u>001</u>	May 31, 2011
<u>AB</u>		<u>10MG</u>	<u>A090551</u>	<u>002</u>	May 31, 2011
<u>AB</u>	WOCKHARDT	<u>5MG</u>	<u>A091267</u>	<u>001</u>	May 31, 2011
<u>AB</u>		<u>10MG</u>	<u>A091267</u>	<u>002</u>	May 31, 2011
<u>AB</u>	ZYDUS PHARMS USA INC	<u>5MG</u>	<u>A090100</u>	<u>001</u>	Oct 24, 2012
<u>AB</u>		<u>10MG</u>	<u>A090100</u>	<u>002</u>	Oct 24, 2012

TABLET, ORALLY DISINTEGRATING; ORAL

ARICEPT ODT

<u>AB</u>	EISAI INC	<u>5MG</u>	<u>N021720</u>	<u>001</u>	Oct 18, 2004
<u>AB</u>	+	<u>10MG</u>	<u>N021720</u>	<u>002</u>	Oct 18, 2004

DONEPEZIL HYDROCHLORIDE

<u>AB</u>	BARR	<u>5MG</u>	<u>A078388</u>	<u>002</u>	Nov 26, 2010
<u>AB</u>		<u>10MG</u>	<u>A078388</u>	<u>001</u>	Nov 26, 2010
<u>AB</u>	MACLEODS PHARMS LTD	<u>5MG</u>	<u>A201787</u>	<u>001</u>	Dec 14, 2012
<u>AB</u>		<u>10MG</u>	<u>A201787</u>	<u>002</u>	Dec 14, 2012
<u>AB</u>	SANDOZ	<u>5MG</u>	<u>A091198</u>	<u>001</u>	May 10, 2011
<u>AB</u>		<u>10MG</u>	<u>A091198</u>	<u>002</u>	May 10, 2011
<u>AB</u>	UNICHEM LABS LTD	<u>5MG</u>	<u>A204831</u>	<u>001</u>	Nov 10, 2016
<u>AB</u>		<u>10MG</u>	<u>A204831</u>	<u>002</u>	Nov 10, 2016
<u>AB</u>	ZYDUS PHARMS USA INC	<u>5MG</u>	<u>A090175</u>	<u>001</u>	May 10, 2011
<u>AB</u>		<u>10MG</u>	<u>A090175</u>	<u>002</u>	May 10, 2011

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

NAMZARIC

FOREST LABS LLC	10MG; 7MG	N206439	003	Jul 18, 2016
	10MG; 14MG	N206439	001	Dec 23, 2014
	10MG; 21MG	N206439	004	Jul 18, 2016
+	10MG; 28MG	N206439	002	Dec 23, 2014

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HYDROCHLORIDE

<u>AP</u>	+	<u>HOSPIRA</u>	<u>40MG/ML</u>	<u>N018132</u>	<u>001</u>
<u>AP</u>	+		<u>80MG/100ML</u>	<u>N018132</u>	<u>002</u>
<u>AP</u>	+		<u>80MG/ML</u>	<u>N018132</u>	<u>004</u>
<u>AP</u>	+		<u>160MG/100ML</u>	<u>N018132</u>	<u>003</u>
<u>AP</u>	+	<u>LUITPOLD</u>	<u>40MG/ML</u>	<u>A070799</u>	<u>001</u>
<u>AP</u>	+		<u>80MG/ML</u>	<u>A070820</u>	<u>001</u>
<u>AP</u>	+		<u>160MG/ML</u>	<u>A070826</u>	<u>001</u>

DOPAMINE HYDROCHLORIDE AND DEXTROSE 5%

<u>AP</u>	+	<u>B BRAUN</u>	<u>80MG/100ML</u>	<u>N019099</u>	<u>002</u>
<u>AP</u>	+		<u>320MG/100ML</u>	<u>N019099</u>	<u>004</u>

DOPAMINE HYDROCHLORIDE AND DEXTROSE 5% IN PLASTIC CONTAINER

<u>AP</u>	+	<u>B BRAUN</u>	<u>160MG/100ML</u>	<u>N019099</u>	<u>003</u>
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DOPAMINE HYDROCHLORIDE IN DEXTROSE 5% IN PLASTIC CONTAINER

<u>AP</u>	+	<u>BAXTER HLTHCARE</u>	<u>80MG/100ML</u>	<u>N019615</u>	<u>001</u>
<u>AP</u>	+		<u>160MG/100ML</u>	<u>N019615</u>	<u>002</u>
<u>AP</u>	+		<u>320MG/100ML</u>	<u>N019615</u>	<u>003</u>
<u>AP</u>	+	<u>HOSPIRA</u>	<u>80MG/100ML</u>	<u>N018826</u>	<u>001</u>
<u>AP</u>	+		<u>160MG/100ML</u>	<u>N018826</u>	<u>002</u>
<u>AP</u>	+		<u>320MG/100ML</u>	<u>N018826</u>	<u>003</u>

DOPAMINE HYDROCHLORIDE AND DEXTROSE 5% IN PLASTIC CONTAINER

+	<u>B BRAUN</u>	<u>40MG/100ML</u>	N019099	001	Oct 15, 1986
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DOPAMINE HYDROCHLORIDE IN DEXTROSE 5% IN PLASTIC CONTAINER

+	<u>BAXTER HLTHCARE</u>	<u>640MG/100ML</u>	N019615	004	Mar 27, 1987
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DORIPENEM

INJECTABLE; IV (INFUSION)

DORIBAX

SHIONOGI INC	250MG/VIAL	N022106	002	Oct 05, 2010
+	500MG/VIAL	N022106	001	Oct 12, 2007

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PRESCRIPTION DRUG PRODUCT LIST

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MELOXICAM

TABLET; ORAL

MELOXICAM

<u>AB</u>	UNICHEM	<u>7.5MG</u>	<u>A077927</u>	<u>001</u>	Dec 20, 2006
<u>AB</u>		<u>15MG</u>	<u>A077927</u>	<u>002</u>	Dec 20, 2006
<u>AB</u>	YUNG SHIN PHARM	<u>7.5MG</u>	<u>A077918</u>	<u>001</u>	Dec 07, 2006
<u>AB</u>		<u>15MG</u>	<u>A077918</u>	<u>002</u>	Dec 07, 2006
<u>AB</u>	ZYDUS PHARMS USA	<u>7.5MG</u>	<u>A077921</u>	<u>001</u>	Jul 19, 2006
<u>AB</u>		<u>15MG</u>	<u>A077921</u>	<u>002</u>	Jul 19, 2006

MOBIC

<u>AB</u>	BOEHRINGER INGELHEIM	<u>7.5MG</u>	<u>N020938</u>	<u>001</u>	Apr 13, 2000
<u>AB</u>	+	<u>15MG</u>	<u>N020938</u>	<u>002</u>	Aug 23, 2000

MELPHALAN

TABLET; ORAL

ALKERAN

+ APOTEX INC

2MG

N014691 002

MELPHALAN HYDROCHLORIDE

INJECTABLE; INJECTION

ALKERAN

<u>AP</u>	+	APOTEX INC	<u>EQ 50MG BASE/VIAL</u>	<u>N020207</u>	<u>001</u>	Nov 18, 1992
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MELPHALAN HYDROCHLORIDE

<u>AP</u>	ACTAVIS LLC	<u>EQ 50MG BASE/VIAL</u>	<u>A206018</u>	<u>001</u>	Dec 19, 2016
<u>AP</u>	MYLAN INSTITUTIONAL	<u>EQ 50MG BASE/VIAL</u>	<u>A090270</u>	<u>001</u>	Jun 09, 2009
<u>AP</u>	PAR STERILE PRODUCTS	<u>EQ 50MG BASE/VIAL</u>	<u>A204773</u>	<u>001</u>	Aug 22, 2016
<u>AP</u>	WEST-WARD PHARMS INT	<u>EQ 50MG BASE/VIAL</u>	<u>A090303</u>	<u>001</u>	Oct 28, 2010

POWDER; IV (INFUSION)

EVOMELA

SPECTRUM PHARMS

EQ 50MG BASE/VIAL

N207155 001 Mar 10, 2016

MEMANTINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

MEMANTINE HYDROCHLORIDE

<u>AB</u>	AMNEAL PHARMS	<u>7MG</u>	<u>A205825</u>	<u>001</u>	Oct 12, 2016
<u>AB</u>		<u>14MG</u>	<u>A205825</u>	<u>002</u>	Oct 12, 2016
<u>AB</u>		<u>21MG</u>	<u>A205825</u>	<u>003</u>	Oct 12, 2016
<u>AB</u>		<u>28MG</u>	<u>A205825</u>	<u>004</u>	Oct 12, 2016
<u>AB</u>	APOTEX INC	<u>7MG</u>	<u>A206135</u>	<u>001</u>	Nov 22, 2016
<u>AB</u>		<u>14MG</u>	<u>A206135</u>	<u>002</u>	Nov 22, 2016
<u>AB</u>		<u>21MG</u>	<u>A206135</u>	<u>003</u>	Nov 22, 2016
<u>AB</u>		<u>28MG</u>	<u>A206135</u>	<u>004</u>	Nov 22, 2016
<u>AB</u>	LUPIN LTD	<u>7MG</u>	<u>A206028</u>	<u>001</u>	Sep 28, 2016
<u>AB</u>		<u>14MG</u>	<u>A206028</u>	<u>002</u>	Sep 28, 2016
<u>AB</u>		<u>21MG</u>	<u>A206028</u>	<u>003</u>	Sep 28, 2016
<u>AB</u>		<u>28MG</u>	<u>A206028</u>	<u>004</u>	Sep 28, 2016
<u>AB</u>	MYLAN PHARMS INC	<u>7MG</u>	<u>A206032</u>	<u>001</u>	Sep 28, 2016
<u>AB</u>		<u>14MG</u>	<u>A206032</u>	<u>002</u>	Sep 28, 2016
<u>AB</u>		<u>21MG</u>	<u>A206032</u>	<u>003</u>	Sep 28, 2016
<u>AB</u>		<u>28MG</u>	<u>A206032</u>	<u>004</u>	Sep 28, 2016
<u>AB</u>	SUN PHARMA GLOBAL	<u>7MG</u>	<u>A205905</u>	<u>001</u>	Sep 28, 2016
<u>AB</u>		<u>14MG</u>	<u>A205905</u>	<u>002</u>	Sep 28, 2016
<u>AB</u>		<u>21MG</u>	<u>A205905</u>	<u>003</u>	Sep 28, 2016
<u>AB</u>		<u>28MG</u>	<u>A205905</u>	<u>004</u>	Sep 28, 2016

NAMENDA XR

<u>AB</u>	FOREST LABS LLC	<u>7MG</u>	<u>N022525</u>	<u>001</u>	Jun 21, 2010
<u>AB</u>		<u>14MG</u>	<u>N022525</u>	<u>002</u>	Jun 21, 2010
<u>AB</u>		<u>21MG</u>	<u>N022525</u>	<u>003</u>	Jun 21, 2010
<u>AB</u>	+	<u>28MG</u>	<u>N022525</u>	<u>004</u>	Jun 21, 2010

SOLUTION; ORAL

MEMANTINE HYDROCHLORIDE

<u>AA</u>	BIO-PHARM INC	<u>2MG/ML</u>	<u>A205446</u>	<u>001</u>	Dec 07, 2015
<u>AA</u>	MACLEODS PHARMS LTD	<u>2MG/ML</u>	<u>A202790</u>	<u>001</u>	Oct 13, 2015
<u>AA</u>	SILARX PHARMS INC	<u>2MG/ML</u>	<u>A204033</u>	<u>001</u>	Oct 13, 2015

NAMENDA

<u>AA</u>	+	FOREST LABS LLC	<u>2MG/ML</u>	<u>N021627</u>	<u>001</u>	Apr 18, 2005
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TABLET; ORAL

MEMANTINE HYDROCHLORIDE

<u>AB</u>	AJANTA PHARMA LTD	<u>5MG</u>	<u>A206528</u>	<u>001</u>	Nov 30, 2015
<u>AB</u>		<u>10MG</u>	<u>A206528</u>	<u>002</u>	Nov 30, 2015
<u>AB</u>	ALEMBIC PHARMS LTD	<u>5MG</u>	<u>A200891</u>	<u>001</u>	Oct 13, 2015
<u>AB</u>		<u>10MG</u>	<u>A200891</u>	<u>002</u>	Oct 13, 2015
<u>AB</u>	AMNEAL PHARMS	<u>5MG</u>	<u>A090041</u>	<u>001</u>	Apr 10, 2015
<u>AB</u>		<u>10MG</u>	<u>A090041</u>	<u>002</u>	Apr 10, 2015

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PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DOFETILIDE - DOFETILIDE</u>						
A 207058	001				PC	Dec 04, 2016
<u>DOFETILIDE - DOFETILIDE</u>						
A 207058	002				PC	Dec 04, 2016
<u>DOFETILIDE - DOFETILIDE</u>						
A 207058	003				PC	Dec 04, 2016
<u>DOFETILIDE - TIKOSYN</u>						
N 020931	001 6124363	Oct 09, 2018				
<u>DOFETILIDE - TIKOSYN</u>						
N 020931	002 6124363	Oct 09, 2018				
<u>DOFETILIDE - TIKOSYN</u>						
N 020931	003 6124363	Oct 09, 2018				
<u>DOLUTEGRAVIR SODIUM - TIVICAY</u>						
N 204790	001 8129385	Oct 05, 2027	DS DP		M-166	Jul 30, 2018
	9242986	Dec 08, 2029	DS DP		NCE	Aug 12, 2018
<u>DOLUTEGRAVIR SODIUM - TIVICAY</u>						
N 204790	002 8129385	Oct 05, 2027	DS DP		NCE	Aug 12, 2018
	9242986	Dec 08, 2029	DS DP			
<u>DOLUTEGRAVIR SODIUM - TIVICAY</u>						
N 204790	003 8129385	Oct 05, 2027	DS DP		NCE	Aug 12, 2018
	9242986	Dec 08, 2029	DS DP			
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>						
N 022568	001 8481565	Oct 04, 2026	DP			
<u>DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC</u>						
N 206439	001 8039009	Mar 24, 2029	U-1641			
	8039009*PED	Sep 24, 2029				
	8058291	Dec 05, 2029	U-1641			
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-1641			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-1641			
	8283379*PED	May 22, 2026				
	8293794	Nov 22, 2025	DP			
	8329752	Nov 22, 2025	DP			
	8329752*PED	May 22, 2026				
	8338485	Nov 22, 2025	DP			
	8338486	Nov 22, 2025	U-1641			
	8362085	Nov 22, 2025	U-1641			
	8362085*PED	May 22, 2026				
	8580858	Nov 22, 2025	U-1641			
	8598233	Nov 22, 2025	DP			
	8598233*PED	May 22, 2026				
<u>DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC</u>						
N 206439	002 8039009	Mar 24, 2029	U-1641			
	8039009*PED	Sep 24, 2029				
	8058291	Dec 05, 2029	U-1641			
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-1641			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-1641			
	8283379*PED	May 22, 2026				
	8293794	Nov 22, 2025	DP			
	8329752	Nov 22, 2025	DP			
	8329752*PED	May 22, 2026				
	8338485	Nov 22, 2025	DP			
	8338486	Nov 22, 2025	U-1641			
	8362085	Nov 22, 2025	U-1641			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC</u>						
N 206439 002	8362085*PED	May 22, 2026				
	8580858	Nov 22, 2025	U-1641			
	8598233	Nov 22, 2025	DP			
	8598233*PED	May 22, 2026				
<u>DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC</u>						
N 206439 003	8039009	Mar 24, 2029	U-1641			
	8039009*PED	Sep 24, 2029				
	8058291	Dec 05, 2029	U-1641			
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-1641			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-1641			
	8283379*PED	May 22, 2026				
	8293794	Nov 22, 2025	DP			
	8329752	Nov 22, 2025	DP			
	8329752*PED	May 22, 2026				
	8338485	Nov 22, 2025	DP			
	8338486	Nov 22, 2025	U-1641			
	8362085	Nov 22, 2025	U-1641			
	8362085*PED	May 22, 2026				
	8580858	Nov 22, 2025	U-1641			
	8598233	Nov 22, 2025	DP			
	8598233*PED	May 22, 2026				
<u>DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC</u>						
N 206439 004	8039009	Mar 24, 2029	U-1641			
	8039009*PED	Sep 24, 2029				
	8058291	Dec 05, 2029	U-1641			
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-1641			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-1641			
	8283379*PED	May 22, 2026				
	8293794	Nov 22, 2025	DP			
	8329752	Nov 22, 2025	DP			
	8329752*PED	May 22, 2026				
	8338485	Nov 22, 2025	DP			
	8338486	Nov 22, 2025	U-1641			
	8362085	Nov 22, 2025	U-1641			
	8362085*PED	May 22, 2026				
	8580858	Nov 22, 2025	U-1641			
	8598233	Nov 22, 2025	DP			
	8598233*PED	May 22, 2026				
<u>DORIPENEM - DORIBAX</u>						
N 022106 001	8247402	Mar 30, 2021	DS DP			
<u>DORIPENEM - DORIBAX</u>						
N 022106 002	8247402	Mar 30, 2021	DS DP			
<u>DOXEPIH HYDROCHLORIDE - SILENOR</u>						
N 022036 001	6211229	Feb 17, 2020	U-620			
	7915307	Aug 24, 2027	U-620			
	8513299	Sep 07, 2030	U-620			
	9107898	May 01, 2028	U-620			
	9486437	May 18, 2027	U-620			
<u>DOXEPIH HYDROCHLORIDE - SILENOR</u>						
N 022036 002	6211229	Feb 17, 2020	U-620			
	7915307	Aug 24, 2027	U-620			
	8513299	Sep 07, 2030	U-620			
	9107898	May 01, 2028	U-620			
	9486437	May 18, 2027	U-620			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DOXYCYCLINE - ORACEA</u>						
N 050805 001	5789395	Aug 30, 2016	U-925	Y		
	5919775	Aug 30, 2016	U-925	Y		
	7211267	Apr 05, 2022	U-925			
	7232572	Apr 05, 2022	U-925			
	7749532	Dec 19, 2027	DP U-1063			
	8206740	Dec 24, 2025	DP U-925			
	8394405	Apr 07, 2024	DP U-925			
	8394406	Apr 07, 2024	DP U-925			
	8470364	Apr 07, 2024	DP U-925			
	8603506	Apr 05, 2022	U-1063			
	8709478	Apr 07, 2024	U-1063			
	9241946	Apr 05, 2022	U-1063			
<u>DOXYCYCLINE HYCLATE - DOXYCYCLINE HYCLATE</u>						
A 090431 003					PC	Nov 19, 2016
<u>DOXYCYCLINE HYCLATE - DOXYCYCLINE HYCLATE</u>						
A 090431 005					PC	Nov 15, 2016
<u>DOXYCYCLINE HYCLATE - DORYX</u>						
N 050795 001	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
<u>DOXYCYCLINE HYCLATE - DORYX</u>						
N 050795 002	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
<u>DOXYCYCLINE HYCLATE - DORYX</u>						
N 050795 003	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
<u>DOXYCYCLINE HYCLATE - DORYX</u>						
N 050795 004	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
<u>DOXYCYCLINE HYCLATE - DORYX</u>						
N 050795 005	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
<u>DOXYCYCLINE HYCLATE - DORYX</u>						
N 050795 006	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
<u>DOXYCYCLINE HYCLATE - DORYX MPC</u>						
N 050795 007	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
	9295652	Oct 23, 2034	DP U-918			
	9446057	Dec 23, 2034	DP U-918			
	9511031	Oct 23, 2034	DP			
<u>DOXYCYCLINE HYCLATE - DORYX MPC</u>						
N 050795 008	6958161	Dec 15, 2022	DP U-918			
	8715724	Feb 03, 2028	DP			
	9295652	Oct 23, 2034	DP U-918			
	9446057	Dec 23, 2034	DP U-918			
	9511031	Oct 23, 2034	DP			
<u>DOXYLAMINE SUCCINATE; PYRIDOXINE HYDROCHLORIDE - DICLEGIS</u>						
N 021876 001	6340695	Jun 21, 2021	DP U-1382			
	7560122	Jan 25, 2019	DP			
<u>DRONEDARONE HYDROCHLORIDE - MULTAQ</u>						
N 022425 001	5223510	Jul 26, 2016	DS DP U-992			
	5223510	Jul 26, 2016	DS DP U-1261			
	7323493	Jun 19, 2018	DP			
	8318800	Jun 19, 2018	DP			
	8410167	Apr 16, 2029	U-1387			
	8410167	Apr 16, 2029	U-1388			
	8602215	Jun 30, 2031	U-1473			

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<u>MECHLORETHAMINE HYDROCHLORIDE - VALCHLOR</u>						
N 202317 001	7838564	Mar 07, 2026	DP		NDF	Aug 23, 2016
	7872050	Jul 08, 2029	U-1427		ODE	Aug 23, 2020
	8450375	Mar 07, 2026	DP			
	8501818	Mar 07, 2026	DP			
	8501819	Mar 07, 2026	U-1427			
	9382191	Mar 07, 2026	DP			
<u>MEDROXYPROGESTERONE ACETATE - DEPO-SUBO PROVERA 104</u>						
N 021583 001	6495534	May 15, 2020	DP			
<u>MEGESTROL ACETATE - MEGACE ES</u>						
N 021778 001	6592903	Sep 21, 2020	DP			
	7101576	Apr 22, 2024	U-755			
	9040088	Apr 22, 2024	U-755			
	9101540	Apr 22, 2024	DP U-755			
	9101549	Apr 22, 2024	U-755			
	9107827	Apr 22, 2024	U-755			
<u>MELOXICAM - MOBIC</u>						
N 021530 001	6184220	Mar 25, 2019	DP			
<u>MELOXICAM - VIVLODEX</u>						
N 207233 001	9526734	Mar 31, 2033	DP		NP	Oct 22, 2018
<u>MELOXICAM - VIVLODEX</u>						
N 207233 002	9526734	Mar 31, 2033	DP		NP	Oct 22, 2018
<u>MELPHALAN HYDROCHLORIDE - EVOMELA</u>						
N 207155 001	8410077	Mar 13, 2029	DP		ODE	Mar 10, 2023
	9200088	Mar 13, 2029	DP			
<u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>						
N 022525 001	8039009	Mar 24, 2029	U-539		M-138	Jul 03, 2017
	8039009*PED	Sep 24, 2029			PED	Jan 03, 2018
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-539			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-539			
	8283379*PED	May 22, 2026				
	8329752	Nov 22, 2025	DP			
	8329752*PED	May 22, 2026				
	8362085	Nov 22, 2025	U-539			
	8362085*PED	May 22, 2026				
<u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>						
N 022525 002	8039009	Mar 24, 2029	U-539		M-138	Jul 03, 2017
	8039009*PED	Sep 24, 2029			PED	Jan 03, 2018
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-539			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-539			
	8283379*PED	May 22, 2026				
	8329752	Nov 22, 2025	DP			
	8329752*PED	May 22, 2026				
	8362085	Nov 22, 2025	U-539			
	8362085*PED	May 22, 2026				
<u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>						
N 022525 003	8039009	Mar 24, 2029	U-539		M-138	Jul 03, 2017
	8039009*PED	Sep 24, 2029			PED	Jan 03, 2018
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-539			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-539			
	8283379*PED	May 22, 2026				
	8329752	Nov 22, 2025	DP			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>						
N 022525 003	8329752*PED	May 22, 2026				
	8362085	Nov 22, 2025	U-539			
	8362085*PED	May 22, 2026				
<u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>						
N 022525 004	8039009	Mar 24, 2029	U-539		M-138	Jul 03, 2017
	8039009*PED	Sep 24, 2029			PED	Jan 03, 2018
	8168209	Nov 22, 2025	DP			
	8168209*PED	May 22, 2026				
	8173708	Nov 22, 2025	U-539			
	8173708*PED	May 22, 2026				
	8283379	Nov 22, 2025	U-539			
	8283379*PED	May 22, 2026				
	8329752	Nov 22, 2025	DP			
	8329752*PED	May 22, 2026				
	8362085	Nov 22, 2025	U-539			
	8362085*PED	May 22, 2026				
	8598233	Nov 22, 2025	DP			
	8598233*PED	May 22, 2026				
<u>MENOTROPINS (FSH;LH); MENOTROPINS (FSH;LH) - MENOPUR</u>						
N 021663 001					D-139	Feb 19, 2017
<u>MENTHOL; METHYL SALICYLATE - SALONPAS</u>						
N 022029 001	8809615	Jan 03, 2030	DP			
	9233184	Aug 01, 2027	DP			
<u>MENTHOL; METHYL SALICYLATE - SALONPAS</u>						
N 022029 002	8809615	Jan 03, 2030	DP			
	9233184	Aug 01, 2027	DP			
<u>MEQUINOL; TRETINOIN - SOLAGE</u>						
N 020922 001	6353029	Aug 24, 2020				
<u>MERCAPTOPURINE - PURIXAN</u>						
N 205919 001					ODE	Apr 28, 2021
<u>MESALAMINE - SFROWASA</u>						
N 019618 002	7645801	Jul 24, 2027	DS DP			
<u>MESALAMINE - CANASA</u>						
N 021252 001					M-187	Sep 02, 2019
<u>MESALAMINE - CANASA</u>						
N 021252 002	8217083	Jun 06, 2028	DP			
	8436051	Jun 06, 2028	DP			
<u>MESALAMINE - ASACOL HD</u>						
N 021830 001	6893662	Nov 15, 2021	DP U-141			
	8580302	Nov 15, 2021	DP			
	9089492	Nov 15, 2021	DP			
<u>MESALAMINE - LIALDA</u>						
N 022000 001	6773720	Jun 08, 2020	DP			
<u>MESALAMINE - APRISO</u>						
N 022301 001	6551620	Apr 20, 2018	DS DP U-907			
	8337886	Apr 20, 2018	DP U-1310			
	8496965	Apr 20, 2018	DP			
	8865688	May 01, 2030	U-1310			
	8911778	Apr 20, 2018	DP U-1310			
	8940328	Apr 20, 2018	DP			
	8956647	Apr 20, 2018	DP			
<u>MESALAMINE - DELZICOL</u>						
N 204412 001	6649180	Apr 13, 2020	DP			


EXHIBIT 10

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New Drug Application (NDA): 022525
Company: FOREST LABS LLC

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- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022525Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022525Orig1s000SumR.pdf)

Products on NDA 022525



CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
NAMENDA XR	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	No
NAMENDA XR	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	No
NAMENDA XR	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	No

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
NAMENDA XR	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	Yes

Showing 1 to 4 of 4 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 022525**Labels for NDA 022525****Therapeutic Equivalents for NDA 022525****NAMENDA XR****CAPSULE, EXTENDED RELEASE;ORAL; 7MG****TE Code = AB**

CSV

Excel

Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
NAMENDA XR	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB

Showing 1 to 8 of 8 entries

CAPSULE, EXTENDED RELEASE;ORAL; 14MG**TE Code = AB**

CSV	Excel	Print
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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
NAMENDA XR	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB

Showing 1 to 8 of 8 entries

CAPSULE, EXTENDED RELEASE;ORAL; 21MG
TE Code = AB

CSV	Excel	Print
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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
NAMENDA XR	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB

Showing 1 to 8 of 8 entries

CAPSULE, EXTENDED RELEASE;ORAL; 28MG**TE Code = AB**

CSV	Excel	Print
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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB
NAMENDA XR	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB

Showing 1 to 8 of 8 entries

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
+ NAMENDA XR	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	No
+ NAMENDA XR	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	No
+ NAMENDA XR	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	No
+ NAMENDA XR	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	Yes	Yes

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205825	AMNEAL PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205784	ANCHEN PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206135	APOTEX INC
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206028	LUPIN LTD
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206032	MYLAN
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205905	SUN PHARM
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	203293	ZYDUS PHARMS
NAMENDA XR	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB	022525	FOREST LABS LLC

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205825	AMNEAL PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205784	ANCHEEN PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206135	APOTEX INC
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206028	LUPIN LTD
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206032	MYLAN
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205905	SUN PHARM
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	203293	ZYDUS PHARMS
NAMENDA XR	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB	022525	FOREST LABS LLC

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205825	AMNEAL PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205784	ANCHEEN PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206135	APOTEX INC
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206028	LUPIN LTD
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206032	MYLAN
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205905	SUN PHARM
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	203293	ZYDUS PHARMS
NAMENDA XR	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB	022525	FOREST LABS LLC

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205825	AMNEAL PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205784	ANCHEN PHARMS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206135	APOTEX INC
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206028	LUPIN LTD
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	206032	MYLAN
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	205905	SUN PHARM
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	No	AB	203293	ZYDUS PHARMS
NAMENDA XR	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	Yes	AB	022525	FOREST LABS LLC

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Product Details for NDA 022525

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NAMENDA XR (MEMANTINE HYDROCHLORIDE)
7MG

Marketing Status: Prescription

Active Ingredient: MEMANTINE HYDROCHLORIDE

Proprietary Name: NAMENDA XR

Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL

Strength: 7MG

Reference Listed Drug: Yes

Reference Standard: No

TE Code: AB

Application Number: N022525

Product Number: 001

Approval Date: Jun 21, 2010

Applicant Holder Full Name: FOREST LABORATORIES LLC

Marketing Status: Prescription

Patent and Exclusivity Information ([patent_info.cfm?](#)

[Product_No=001&Appl_No=022525&Appl_type=N](#))

NAMENDA XR (MEMANTINE HYDROCHLORIDE) 14MG	Marketing Status: Prescription
Active Ingredient: MEMANTINE HYDROCHLORIDE Proprietary Name: NAMENDA XR Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL Strength: 14MG Reference Listed Drug: Yes Reference Standard: No TE Code: AB Application Number: N022525 Product Number: 002 Approval Date: Jun 21, 2010 Applicant Holder Full Name: FOREST LABORATORIES LLC Marketing Status: Prescription <u>Patent and Exclusivity Information (patent_info.cfm? Product No=002&Appl No=022525&Appl type=N)</u>	
NAMENDA XR (MEMANTINE HYDROCHLORIDE) 21MG	Marketing Status: Prescription
Active Ingredient: MEMANTINE HYDROCHLORIDE Proprietary Name: NAMENDA XR Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL Strength: 21MG Reference Listed Drug: Yes Reference Standard: No TE Code: AB Application Number: N022525 Product Number: 003 Approval Date: Jun 21, 2010 Applicant Holder Full Name: FOREST LABORATORIES LLC Marketing Status: Prescription <u>Patent and Exclusivity Information (patent_info.cfm? Product No=003&Appl No=022525&Appl type=N)</u>	
NAMENDA XR (MEMANTINE HYDROCHLORIDE) 28MG	Marketing Status: Prescription
Active Ingredient: MEMANTINE HYDROCHLORIDE Proprietary Name: NAMENDA XR Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL Strength: 28MG	

Reference Listed Drug: Yes

Reference Standard: Yes

TE Code: AB

Application Number: N022525

Product Number: 004

Approval Date: Jun 21, 2010

Applicant Holder Full Name: FOREST LABORATORIES LLC

Marketing Status: Prescription

Patent and Exclusivity Information (patent_info.cfm?

Product_No=004&Appl_No=022525&Appl_type=N)

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Patent and Exclusivity for: N022525

Product 001

MEMANTINE HYDROCHLORIDE (NAMENDA XR) CAPSULE, EXTENDED RELEASE 7MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
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Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8039009	03/24/2029			U-539		11/16/20
001	8039009*PED	09/24/2029					
001	8168209	11/22/2025		DP			04/23/20
001	8168209*PED	05/22/2026					
001	8173708	11/22/2025			U-539		04/23/20
001	8173708*PED	05/22/2026					
001	8283379	11/22/2025			U-539		04/23/20
001	8283379*PED	05/22/2026					
001	8329752	11/22/2025		DP			04/23/20
001	8329752*PED	05/22/2026					
001	8362085	11/22/2025			U-539		04/22/20
001	8362085*PED	05/22/2026					

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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Patent and Exclusivity for: N022525

Product 002

MEMANTINE HYDROCHLORIDE (NAMENDA XR) CAPSULE, EXTENDED RELEASE 14MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
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Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
002	8039009	03/24/2029			U-539		
002	8039009*PED	09/24/2029					
002	8168209	11/22/2025		DP			
002	8168209*PED	05/22/2026					
002	8173708	11/22/2025			U-539		
002	8173708*PED	05/22/2026					
002	8283379	11/22/2025			U-539		
002	8283379*PED	05/22/2026					
002	8329752	11/22/2025		DP			
002	8329752*PED	05/22/2026					
002	8362085	11/22/2025			U-539		
002	8362085*PED	05/22/2026					

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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Patent and Exclusivity for: N022525

Product 003

MEMANTINE HYDROCHLORIDE (NAMENDA XR) CAPSULE, EXTENDED RELEASE 21MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
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Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
003	8039009	03/24/2029			U-539		
003	8039009*PED	09/24/2029					
003	8168209	11/22/2025		DP			
003	8168209*PED	05/22/2026					
003	8173708	11/22/2025			U-539		
003	8173708*PED	05/22/2026					
003	8283379	11/22/2025			U-539		
003	8283379*PED	05/22/2026					
003	8329752	11/22/2025		DP			
003	8329752*PED	05/22/2026					
003	8362085	11/22/2025			U-539		
003	8362085*PED	05/22/2026					

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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Patent and Exclusivity for: N022525

Product 004

MEMANTINE HYDROCHLORIDE (NAMENDA XR) CAPSULE, EXTENDED RELEASE 28MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
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Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
004	8039009	03/24/2029			U-539		
004	8039009*PED	09/24/2029					
004	8168209	11/22/2025		DP			
004	8168209*PED	05/22/2026					
004	8173708	11/22/2025			U-539		
004	8173708*PED	05/22/2026					
004	8283379	11/22/2025			U-539		
004	8283379*PED	05/22/2026					
004	8329752	11/22/2025		DP			
004	8329752*PED	05/22/2026					
004	8362085	11/22/2025			U-539		
004	8362085*PED	05/22/2026					
004	8598233	11/22/2025		DP			
004	8598233*PED	05/22/2026					

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet/?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)




 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

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Abbreviated New Drug Application (ANDA): 205825

Company: AMNEAL PHARMS

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=205825\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=205825)

Products on ANDA 205825

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Showing 1 to 4 of 4 entries

Approval Date(s) and History, Letters, Labels, Reviews for ANDA 205825**Original Approvals or Tentative Approvals**

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
10/12/2016	ORIG-1	Approval		STANDARD		Label is not available on this site.

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Therapeutic Equivalents for ANDA 205825

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drugs@FDA: FDA Approved Drug Products


Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
10/12/2016	ORIG-1	Approval		STANDARD		Label is not available on this site.	

Drugs@FDA: FDA Approved Drug Products

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)


 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet/?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)



 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

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Abbreviated New Drug Application (ANDA): 205784
Company: ANCHEN PHARMS

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=205784\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=205784)

Products on ANDA 205784

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Showing 1 to 4 of 4 entries

Approval Date(s) and History, Letters, Labels, Reviews for ANDA 205784**Original Approvals or Tentative Approvals**

CSV

Excel

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
06/09/2017	ORIG-1	Approval		STANDARD		Label is not available on this site.

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Therapeutic Equivalents for ANDA 205784

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drugs@FDA: FDA Approved Drug Products


Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
06/09/2017	ORIG-1	Approval		STANDARD		Label is not available on this site.	

Drugs@FDA: FDA Approved Drug Products

 **SHARE** ([HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process))


 **TWEET** ([HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS](https://twitter.com/intent/tweet/?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process))



 **EMAIL** ([MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process))

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Abbreviated New Drug Application (ANDA): 206135
Company: APOTEX INC

 **EMAIL** ([MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=206135](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=206135))

Products on ANDA 206135

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Showing 1 to 4 of 4 entries

Approval Date(s) and History, Letters, Labels, Reviews for ANDA 206135**Original Approvals or Tentative Approvals**

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
11/22/2016	ORIG-1	Approval		STANDARD		Label is not available on this site.

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Therapeutic Equivalents for ANDA 206135

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drugs@FDA: FDA Approved Drug Products


Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
11/22/2016	ORIG-1	Approval		STANDARD		Label is not available on this site.	

Drugs@FDA: FDA Approved Drug Products

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)


 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet/?text=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)



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Abbreviated New Drug Application (ANDA): 206028
Company: LUPIN LTD

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=206028\)](mailto:?subject=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=206028)

Products on ANDA 206028

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Showing 1 to 4 of 4 entries

Approval Date(s) and History, Letters, Labels, Reviews for ANDA 206028**Original Approvals or Tentative Approvals**

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Pati
09/28/2016	ORIG-1	Approval		STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/014121Orig1s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/014121Orig1s01.pdf)

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Labels for ANDA 206028**Therapeutic Equivalents for ANDA 206028**

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drugs@FDA: FDA Approved Drug Products


Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
09/28/2016	ORIG-1	Approval		STANDARD	Label (PDF) Letter (PDF)		https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206028Orig1s000lbl.pdf https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/206028Orig1s000l.pdf

Drugs@FDA: FDA Approved Drug Products

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet/?text=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)




 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

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Abbreviated New Drug Application (ANDA): 206032

Company: MYLAN

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=206032\)](mailto:?subject=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=206032)

Products on ANDA 206032

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	F
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

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Approval Date(s) and History, Letters, Labels, Reviews for ANDA 206032**Original Approvals or Tentative Approvals**

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Pati
09/28/2016	ORIG-1	Approval		STANDARD	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/014181Orig1s01.pdf)

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Therapeutic Equivalents for ANDA 206032

Drugs@FDA: FDA Approved Drug Products


Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
+ MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drugs@FDA: FDA Approved Drug Products


Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
09/28/2016	ORIG-1	Approval		STANDARD	Letter (PDF)	Label is not available on this site.	https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/206032Orig1s000I

Drugs@FDA: FDA Approved Drug Products

 [SHARER \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.Process)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.Process)



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Abbreviated New Drug Application (ANDA): 205905

Company: SUN PHARM

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=205905\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=Overview.Process%26VARAPPLNO=205905)

Products on ANDA 205905



CSV

Excel

Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB

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Approval Date(s) and History, Letters, Labels, Reviews for ANDA 205905**Original Approvals or Tentative Approvals**

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
09/28/2016	ORIG-1	Approval		STANDARD	Label (PDF) (https Letter (PDF) (https

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Labels for ANDA 205905**Therapeutic Equivalents for ANDA 205905**

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drugs@FDA: FDA Approved Drug Products

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
09/28/2016	ORIG-1	Approval		STANDARD	Label (PDF) Letter (PDF)		https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205905Orig1s0 https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/205905Orig

Drugs@FDA: FDA Approved Drug Products

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDE
R/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://
WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet?text=drugs@fda: fda approved drug products&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)



e [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FD
A.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=drugs@fda: fda approved drug products&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

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Abbreviated New Drug Application (ANDA): 203293

Company: ZYDUS PHARMS

e [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.
GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=203293\)](mailto:?subject=drugs@fda: fda approved drug products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=203293)

Products on ANDA 203293

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB

Showing 1 to 4 of 4 entries

Approval Date(s) and History, Letters, Labels, Reviews for ANDA 203293**Original Approvals or Tentative Approvals**

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Excel

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
08/03/2017	ORIG-1	Approval		STANDARD	Letter (PDF) (https

Showing 1 to 1 of 1 entries

Therapeutic Equivalents for ANDA 203293

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No
MEMANTINE HYDROCHLORIDE	MEMANTINE HYDROCHLORIDE	28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	AB	No	No

Drugs@FDA: FDA Approved Drug Products

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
08/03/2017	ORIG-1	Approval		STANDARD	Letter (PDF)	Label is not available on this site.	https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203293Orig

Drugs@FDA: FDA Approved Drug Products

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t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet?text=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=basicsearch.process)

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New Drug Application (NDA): 206439

Company: ALLERGAN SALES LLC

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- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206439Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206439Orig1s000SumR.pdf)

Products on NDA 206439



CSV

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Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes

Showing 1 to 4 of 4 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 206439



Original Approvals or Tentative Approvals

CSV	Excel	Print
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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
12/23/2014	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/018439Orig1s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/018439Orig1s01.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/018439Orig1s01.pdf) Summary Review

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Supplements

CSV	Excel	Print
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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
07/18/2016	SUPPL-3	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/018421Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/018421Orig1s001.pdf)
10/06/2015	SUPPL-2	Manufacturing (CMC)	
09/01/2015	SUPPL-1	Manufacturing (CMC)	

Showing 1 to 3 of 3 entries

Labels for NDA 206439

Drugs@FDA: FDA Approved Drug Products

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;14MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;28MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes	Yes
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;7MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
NAMZARIC	DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE	10MG;21MG	CAPSULE, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No


Drugs@FDA: FDA Approved Drug Products


Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes	Url
12/23/2014	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) Letter (PDF) Review Summary Review (PDF)		https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206439lbl.pdf https://www.accessdata.fda.gov/drugsatfda_docs/apletter/2014/206439Orig1s00.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206439Orig1s00.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206439Orig1s00.pdf

Drugs@FDA: FDA Approved Drug Products

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note	Url
07/18/2016	SUPPL-3	Efficacy-Labeling Change With Clinical Data	Label (PDF) Letter (PDF)		https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206439s003lbl.pdf https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/206439Orig1s003ltr.pdf
10/06/2015	SUPPL-2	Manufacturing (CMC)		Label is not available on this site.	
09/01/2015	SUPPL-1	Manufacturing (CMC)		Label is not available on this site.	

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Product Details for NDA 206439

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NAMZARIC (DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE)
10MG;7MG Marketing Status: Prescription

Active Ingredient: DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE

Proprietary Name: NAMZARIC

Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL

Strength: 10MG;7MG

Reference Listed Drug: Yes

Reference Standard: No

TE Code:

Application Number: N206439

Product Number: 003

Approval Date: Jul 18, 2016

Applicant Holder Full Name: ALLERGAN SALES LLC

Marketing Status: Prescription

Patent and Exclusivity Information (patent_info.cfm?Product_No=003&Appl_No=206439&Appl_type=N)

NAMZARIC (DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE)
10MG;14MG Marketing Status: Prescription

Active Ingredient: DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE

Proprietary Name: NAMZARIC

Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL

Strength: 10MG;14MG

Reference Listed Drug: Yes

Reference Standard: No

TE Code:

Application Number: N206439

Product Number: 001

Approval Date: Dec 23, 2014

Applicant Holder Full Name: ALLERGAN SALES LLC

Marketing Status: Prescription

Patent and Exclusivity Information (patent_info.cfm?Product_No=001&Appl_No=206439&Appl_type=N)

NAMZARIC (DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE)
10MG;21MG Marketing Status: Prescription

Active Ingredient: DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE

Proprietary Name: NAMZARIC

Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE; ORAL

Strength: 10MG;21MG

Reference Listed Drug: Yes

Reference Standard: No

TE Code:

Application Number: N206439

Product Number: 004

Approval Date: Jul 18, 2016

Applicant Holder Full Name: ALLERGAN SALES LLC

Marketing Status: Prescription

Patent and Exclusivity Information (patent_info.cfm?Product_No=004&Appl_No=206439&Appl_type=N)

NAMZARIC (DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE)
10MG;28MG

Marketing Status: Prescription

Active Ingredient: DONEPEZIL HYDROCHLORIDE; MEMANTINE
HYDROCHLORIDE

Proprietary Name: NAMZARIC

Dosage Form; Route of Administration: CAPSULE, EXTENDED RELEASE;
ORAL

Strength: 10MG;28MG

Reference Listed Drug: Yes

Reference Standard: Yes

TE Code:

Application Number: N206439

Product Number: 002


Approval Date: Dec 23, 2014


Applicant Holder Full Name: ALLERGAN SALES LLC

Marketing Status: Prescription


Patent and Exclusivity Information (patent_info.cfm?Product_No=002&Appl_No=206439&Appl_type=N)

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Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53 (d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N206439

Product 003

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE (NAMZARIC)
CAPSULE, EXTENDED RELEASE 10MG;7MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Request
003	8039009	03/24/2029			U-1641	
003	8039009*PED	09/24/2029				
003	8058291	12/05/2029			U-1641	
003	8168209	11/22/2025		DP		
003	8168209*PED	05/22/2026				
003	8173708	11/22/2025			U-1641	
003	8173708*PED	05/22/2026				
003	8283379	11/22/2025			U-1641	
003	8283379*PED	05/22/2026				
003	8293794	11/22/2025		DP		
003	8329752	11/22/2025		DP		
003	8329752*PED	05/22/2026				
003	8338485	11/22/2025		DP		
003	8338486	11/22/2025			U-1641	
003	8362085	11/22/2025			U-1641	
003	8362085*PED	05/22/2026				
003	8580858	11/22/2025			U-1641	
003	8598233	11/22/2025		DP		
003	8598233*PED	05/22/2026				

Exclusivity Data


Product No	Exclusivity Code	Exclusivity Expiration
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Additional Information about Patents

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- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N206439

Product 001

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE (NAMZARIC)
CAPSULE, EXTENDED RELEASE 10MG;14MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Request
001	8039009	03/24/2029			U-1641	
001	8039009*PED	09/24/2029				
001	8058291	12/05/2029			U-1641	
001	8168209	11/22/2025		DP		
001	8168209*PED	05/22/2026				
001	8173708	11/22/2025			U-1641	
001	8173708*PED	05/22/2026				
001	8283379	11/22/2025			U-1641	
001	8283379*PED	05/22/2026				
001	8293794	11/22/2025		DP		
001	8329752	11/22/2025		DP		
001	8329752*PED	05/22/2026				
001	8338485	11/22/2025		DP		
001	8338486	11/22/2025			U-1641	
001	8362085	11/22/2025			U-1641	
001	8362085*PED	05/22/2026				
001	8580858	11/22/2025			U-1641	
001	8598233	11/22/2025		DP		
001	8598233*PED	05/22/2026				

Exclusivity Data


Product No	Exclusivity Code	Exclusivity Expiration
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- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
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Patent and Exclusivity for: N206439

Product 004

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE (NAMZARIC)
CAPSULE, EXTENDED RELEASE 10MG;21MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Request
004	8039009	03/24/2029			U-1641	
004	8039009*PED	09/24/2029				
004	8058291	12/05/2029			U-1641	
004	8168209	11/22/2025		DP		
004	8168209*PED	05/22/2026				
004	8173708	11/22/2025			U-1641	
004	8173708*PED	05/22/2026				
004	8283379	11/22/2025			U-1641	
004	8283379*PED	05/22/2026				
004	8293794	11/22/2025		DP		
004	8329752	11/22/2025		DP		
004	8329752*PED	05/22/2026				
004	8338485	11/22/2025		DP		
004	8338486	11/22/2025			U-1641	
004	8362085	11/22/2025			U-1641	
004	8362085*PED	05/22/2026				
004	8580858	11/22/2025			U-1641	
004	8598233	11/22/2025		DP		
004	8598233*PED	05/22/2026				

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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Patent and Exclusivity for: N206439

Product 002

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE (NAMZARIC)
CAPSULE, EXTENDED RELEASE 10MG;28MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Request
002	8039009	03/24/2029			U-1641	
002	8039009*PED	09/24/2029				
002	8058291	12/05/2029			U-1641	
002	8168209	11/22/2025		DP		
002	8168209*PED	05/22/2026				
002	8173708	11/22/2025			U-1641	
002	8173708*PED	05/22/2026				
002	8283379	11/22/2025			U-1641	
002	8283379*PED	05/22/2026				
002	8293794	11/22/2025		DP		
002	8329752	11/22/2025		DP		
002	8329752*PED	05/22/2026				
002	8338485	11/22/2025		DP		
002	8338486	11/22/2025			U-1641	
002	8362085	11/22/2025			U-1641	
002	8362085*PED	05/22/2026				
002	8580858	11/22/2025			U-1641	
002	8598233	11/22/2025		DP		
002	8598233*PED	05/22/2026				

Exclusivity Data

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